IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-65

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Petitioner,*

v.

THE UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE: THE UNITED STATES FOOD AND DRUG ADMINISTRATION; and DONALD KENNEDY Commissioner of the Food and Drug Administration, *Respondents.*

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Petitioner,*

v.

JOSEPH A. CALIFANO, JR., Secretary of Health, Education, and Welfare; DONALD KENNEDY, Commissioner of the Food and Drug Administration; and THE UNITED STATES OF AMERICA, *Respondents.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the District of Columbia Circuit entered in consolidated cases Nos. 75-1845 and 76-1007.

I. OPINION BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit, dated February 13, 1978, has not been reported, but is set forth in its entirety in Appendix D.

II. JURISDICTION

The decree of the United States Court of Appeals for the District of Columbia Circuit was entered February 13, 1978. That court's orders denying a timely petition for a rehearing *en banc,* printed in Appendices E and F, were entered on April 11, 1978.

The jurisdiction of the Supreme Court is invoked pursuant to 28 U.S.C. § 1254(1).

III. QUESTIONS PRESENTED

The central question presented for review by this petition transcends a mere recitation of the errors petitioner Independent Cosmetic Manufacturers and Distributors, Inc. ("ICMAD") sees in the opinion below. What occurred during the 27 month period during which the FDA's cosmetic ingredient labeling regulation was being promulgated is best described by Judge Wilkey in the beginning of his dissenting opinion.

> "In this particular matter the procedural history is embarrassing to the FDA and to the disposition the majority make of this case. If the reader receives the impression that the Commissioner was operating without legal counsel, or with lawyers who preferred to ignore the agency's basic statute and the Administrative Procedure Act, while devising *ad hoc* procedure en route to final regulations, that impression is an accurate reflection of the record." Slip op. at 1 (dissenting opinion), Appendix D at 19a.

The preeminent issue ICMAD requests this Court to review is whether the FDA may disregard procedural safeguards established by Congress and adopt "weird"[1] procedures of its own making instead, thereby denying petitioner's right to meaningfully participate in the rule making proceeding and jeopardizing its members' principal business assets—*i.e.* their trade secrets. Perhaps, more importantly, from the perspective of this petition, can the FDA's ongoing[2] penchant for devising its own procedures contrary to law be allowed to stand as "a model which, if followed by other administrators can be used to insulate their own actions from judicial review."[3] In the context of the opinion below (which never reached the issue of violations of the Administrative Procedure Act ("APA")), the specific questions presented for review are:

1. Whether, in view of the plain language of § 371(f)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA") (21 U.S.C. § 371 (f)(6))[4] and the decision of this Court in *Abbott Laboratories* v. *Gardner,* 387 U.S. 136 (1967), the court of appeals erred in holding that § 371(f)(1) vests jurisdiction to review regulations promulgated by the Food and Drug Administration ("FDA") pursuant to § 371 (e) of the FFDCA and the Fair Packaging and Labeling Act ("FPLA") (15 U.S.C.

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[1] Slip op. at 1 (dissenting opinion), Appendix D at 19a.

[2] *See e.g. Zotos International, Inc.* v. *Kennedy,* No. 77-0218 (D.D.C. April 27, 1978).

[3] Slip op. at 48 (dissenting opinion), Appendix D at 66a.

[4] Unless otherwise specifically noted, all section references are to the FFDCA as codified in 21 U.S.C. § 301 *et seq.*

§§ 1451-61)[5] "exclusively in the court of appeals." Slip op. at 3, Appendix D at 6a.

2. Whether the court of appeals erred in finding that the FDA's gross disregard of the statutory requirements of § 371(e) of the FFDCA and the FPLA was not prejudicial to ICMAD. Slip op. at 12, Appendix D at 15a.

3. Whether the court of appeals erred in holding that ICMAD's petition for review by the court of appeals pursuant to § 371(f) of the FFDCA was untimely. Slip op. at 11, Appendix D at 14a.

IV. STATUTES AND REGULATIONS INVOLVED

The statutory provisions involved in this proceeding (§§ 1454-5 of the Fair Packaging and Labeling Act and § 371 of the Federal Food, Drug and Cosmetic Act) and the relevant regulations (21 C.F.R. §§ 2.63 (a), 2.66, 2.67, 2.68, and 2.69)[6] are lengthy and therefore are set out in pertinent part in Appendix G. A brief summary of the statutory provisions follows.

Section 1455 of the FPLA mandates that the Secretary abide by the procedural requirements of the FFDCA delineated in 21 U.S.C. §§ 371(e), (f), and (g). In brief, the Secretary *must*:

(1) publish all proposals for the issuance, amendment, or repeal of any regulation and provide an opportunity for all interested parties to comment on them (§ 371(e)(1));

[5] Unless otherwise specifically noted, all section references are to the FPLA as codified in 15 U.S.C. § 1451 *et seq.*

[6] Citations in this petition to the FDA's procedural regulations refer to their codification at the time ICMAD's petition for review was filed. The regulations have since been recodified.

(2) act on any proposal by order which cannot become effective until 30 days after the order has been made public (§ 371(e)(1) and (2));

(3) permit, within the 30 day period, any person who will be adversely affected by the order to object to the order specifying with particularity the grounds therefor, and requesting a public hearing upon such objections (§ 371(e)(2));

(4) stay the effectiveness of the portions of the order to which objections have been made (§ 371(e)(2));

(5) publish a notice in the Federal Register specifying the parts of the order which have been stayed by the filing of objections (§ 371(e)(2));

(6) hold a public hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections (§ 371(e)(3)); and

(7) after completion of the hearing, act upon the objections by public order which must be predicated on substantial evidence on the hearing record and set out the detailed findings of fact upon which the order is based (§ 371(e)(3)).

Where there is an actual controversy as to the validity of any order promulgated pursuant to the above-described authority, any aggrieved party may petition a court of appeals for review of such order. 21 U.S.C. § 371(f)(1). In addition, an affected party is entitled to "any other remedies provided for by law." 21 U.S.C. § 371(f)(6).

V. STATEMENT OF THE CASE

A. Summary of this Litigation.

On February 7, 1973, the Commissioner of FDA initiated administrative proceedings which culminated in the Cosmetic Ingredient Labeling Regulation, now codified at 21 C.F.R. § 701.3 *et seq.* At various stages of the proceeding, petitioner ICMAD[1] opposed the issuance of the regulation on both procedural and substantive grounds. Despite ICMAD's opposition to the regulation, the Commissioner issued the final regulation on May 30, 1975.

Recognizing confusion in the law regarding the proper forum for judicial review, ICMAD on August 27, 1975 simultaneously sought declaratory and injunctive relief in the United States District Court for the District of Columbia pursuant to 28 U.S.C. §§ 1331, 2201, and 2202, and petitioned the United States Court of Appeals for the District of Columbia Circuit for direct review under 21 U.S.C. § 371(f)(1).[2]

On October 21, 1975, the district court dismissed ICMAD's complaint on the ground that it had no jurisdiction to hear the action. ICMAD appealed and the appeal was joined with the already pending petition for review in the court of appeals.

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[1] ICMAD is a trade association comprised of small-to-medium sized manufacturers and distributors of cosmetic, skin care, and fragrance products in the United States.

[2] In both actions, ICMAD's claims were essentially the same: (1) that the Commissioner's actions contravened the statutorily-imposed procedural requirements of the APA and the FFDCA; (2) that the Commissioner failed to make specific findings which, by statute, are prerequisites to the issuance of a cosmetic ingredient labeling regulation; and (3) that the regulation, as finally promulgated, violated the FPLA in that it required the divulgence of trade secrets in contravention of 15 U.S.C. § 1454(c)(3).

On January 27, 1977, the court of appeals filed its judgment in both cases; the order of the district court dismissing the complaint was affirmed and ICMAD's petition for review was denied. One year later, on February 13, 1978, the court of appeals entered its judgment and rendered a joint opinion encompassing both proceedings. As characterized by Judge Wilkey:

> "The result of the majority's decision on both of petitioner's pleas is to *deny* ICMAD *any opportunity* to obtain judicial review of the Commissioner's cosmetic labeling regulation *anywhere.*" Slip op. at 3 (dissenting opinion), Appendix D at 21a. (Emphasis in original).

ICMAD filed its suggestion for rehearing *en banc* on February 27, 1978. It was denied on April 11, 1978. *See* Appendices E and F.

B. Statement of Facts.

The facts material to the consideration of the questions presented may be summarized as follows: On February 7, 1973, the Commissioner initiated a rulemaking proceeding intended to culminate in a regulation which would require cosmetic ingredient labeling. In so doing, he was required to find that such regulation was necessary "to prevent the deception of consumers or to facilitate value comparisons." 15 U.S.C. § 1454(c). Where objections to the provisions of the proposed regulation were made by affected parties, such provisions were, according to law, to be automatically stayed pending an evidentiary hearing. 21 U.S.C. § 371(e)(2). On May 30, 1975, the cosmetic ingredient labeling regulation currently in effect was published in the Federal Register. Although objections to the Commissioner's proposal in its various forms were lodged, no evidentiary hearing was ever

held and the Commissioner has yet to publish any findings upon which he based his required determination that the regulation was necessary to prevent consumer deception or to facilitate value comparisons.

By law, any affected party may seek review of a final agency action by filing a petition for review with the court of appeals within ninety days of the effective date of the action. 21 U.S.C. § 371(f)(1). By statutory provision, this remedy is in addition to and not in substitution for any other remedies available at law. 21 U.S.C. § 371(f)(6).

The following summarizes in chronological order the steps which the Commissioner in fact took in promulgating his regulation:

(1) On February 7, 1973, the Commissioner issued a proposed cosmetic ingredient labeling regulation comprised of four subsections and requested comments thereon. 38 Fed. Reg. 3523-25.

(2) On October 17, 1973, the Commissioner responded to substantive issues raised in written comments on the proposed regulation, added a fifth subsection to the proposal, and *for the first time* invited parties to exercise their right to object to the regulation. 38 Fed. Reg. 28912-14. Objections were filed and a hearing requested by several parties.

(3) On July 25, 1974, notice was given of the availability of a "Tentative Revised Final Order" which in the Commissioner's view adequately responded to all of the objections raised by the October 17, 1973 notices and eliminated the need for any public hearing. 39 Fed. Reg. 27181. The Tentative Revised Final Order itself was not published.

(4) On March 3, 1975, the Commissioner proposed twelve new subsections to the regulation which had been proposed and under review since February 7, 1973. These revisions were in large part the result of private discussions with objectors from July 25, 1974 to August 23, 1974. 40 Fed. Reg. 8918-24. On the same date, the Commissioner published a separate document replying to objections filed in response to the October 17, 1973 proposal. 40 Fed. Reg. 8924-26.

(5) Finally, on May 30, 1975, the Commissioner refused to respond to objections concerning the five subsections contained in the October 17, 1973 publication because they were "untimely" and at the same time the Commissioner rejected most of the objections to the twelve added subsections and classified others as "petitions for amendment". 40 Fed. Reg. 23458-60.[9]

For a detailed statement of the facts involved in this controversy, ICMAD respectfully directs this Court's attention to Judge Wilkey's statement of the facts set out in his dissenting opinion. *See* Slip op. at 5-14 (dissenting opinion), Appendix D at 23a-32a.

VI. ARGUMENT

Petitioner anticipates that respondent will argue that this case is not of sufficient importance for this Court to review, that its regulation is in effect, that

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[9] The FDA's discordant approach to the issuance of the cosmetic ingredient labeling regulation is epitomized by the fact that as of this date, over three years after the receipt of ICMAD's "petitions for amendment," no notice of receipt of these petitions has ever been published, no comments have been invited, no hearing held, and no action has been taken by FDA.

ICMAD's members are complying with such regulation, and that any prejudice that might have occurred has ended. But the issue goes much further. First, ICMAD's members are being required to disclose trade secrets the protection of which is crucial to their economic viability. This issue was raised by petitioner before the FDA and, as the record shows, was never dealt with by the FDA. The FDA continues to use arbitrary and unjustified procedures in dealing with such claims.[10] This issue was properly raised below in both the court of appeals and the district court by petitioner and never reached. Second, as eloquently explained by Judge Wilkey in his dissent, this case has relevance far beyond the denial of justice to ICMAD and its members; it goes to the heart of whether aggrieved parties have a forum in which to challenge allegedly unlawful agency action.

> "The majority here achieves a remarkable result: the petitioner is denied relief in the District Court because the Court of Appeals has exclusive jurisdiction; the petitioner is denied relief in this Court of Appeals because petitioner's challenge is 'untimely'; even though it was precisely the weird procedure in the FDA which left the petitioner with neither clear reason nor opportunity to challenge the regulations, 'the attack on the procedure . . . fails because no prejudice has been shown'; and, by lifting of the protective stay on 14 March 1977 with the reasons for decision following eleven months later, the petitioner has been denied any realistic chance of relief by seeking en banc consideration or certiorari. How did Justice assume this shape?? Slip op. at 1 (dissenting opinion), Appendix D at 19a.
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[10] *See e.g. Zotos International, Inc.* v. *Kennedy*, No. 77-0218 (D.D.C. April 27, 1978).

> "I dissent from the majority's position on the grounds that the District Court has subject matter jurisdiction over ICMAD's action and that, in the context of this case, the District Court was the proper forum for ICMAD's challenge. Most emphatically, I also dissent from the majority's conclusion that ICMAD's petition in this Court was not timely filed. These cases present a significant and recurring issue related to the choice of the proper federal forum in which to mount a challenge to federal administrative agency action; *the result here is that federal agency action is totally insulated from judicial review.*" Slip op. at 3 (dissenting opinion), Appendix D at 21a. (Emphasis in original).

The following will demonstrate that the court of appeals erred in holding that § 371(f)(1) of the FFDCA vests exclusive jurisdiction in the court of appeals to review FDA regulations adopted pursuant to the FPLA and the FFDCA and that such decision is contrary to controlling precedents of this Court. Petitioner will also show that the court of appeals erred in holding that ICMAD was not prejudiced by the illegal procedures followed by the FDA and in holding that ICMAD's petition for review to the court of appeals was untimely. Both such holdings involve fundamental questions of federal law which this Court should exercise its power to review.

A. The Court of Appeals Erred in Holding That A Petition for Review Pursuant to Section 371(f) of the FFDCA is the Exclusive Remedy for a Party Adversely Affected by a Regulation Issued by the FDA.

A majority of the court of appeals held that § 371(f)(1) of the FFDCA vests jurisdiction to review regulations promulgated by the FDA pursuant to § 371(e) of that Act and the FPLA "exclusively in

the court of appeals." Slip op. at 3, Appendix D at 6a. This decision contravenes the express language of the review provisions of the FFDCA and its legislative history, and flies in the face of this Court's decision in *Abbott Laboratories* v. *Gardner,* 387 U.S. 136 (1967).

Section 1455 of the FPLA provides in pertinent part:

> "(a) Regulations promulgated by the Secretary [of HEW] under section 1453 or 1454 of this title shall be promulgated, and shall be subject to judicial review, pursuant to the provisions of subsections (e), (f), and (g) of section 371 of Title 21."

Section 371(f)(1) of the FFDCA provides that a party "adversely affected" by an order of the Commissioner may "file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order." The statute then specifically provides in subsection (6) of § 371(f) that "The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

The legislative history of this provision documents Congress' intent that the traditional avenues of judicial review of agency action not be eclipsed by § 371 (f)(1). This Court closely examined that legislative history in *Abbott Laboratories* v. *Gardner, supra.* After noting that exclusivity of remedies is never to be inferred but must be explicitly stated, this Court stated:

> ". . . indeed, a study of the legislative history shows rather conclusively that the specific review

> provisions were designed to give an additional remedy and not to cut down more traditional channels of review.
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> * * *
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> "There is no evidence at all that members of Congress meant to preclude traditional avenues of judicial relief." 387 U.S. at 142.

In *Abbott,* this Court drew an important distinction between the types of cases susceptible to review by courts of appeal and those which should be heard by district courts. This Court stated that the FFDCA and its legislative history show that review in courts of appeal was not intended to be exclusive, but rather was included "primarily as a method of reviewing agency *factual* determinations." *Id.* at 143. (Emphasis in original)." Furthermore:

> "[I]t [is] quite apparent that the special-review procedures provided in § 701(f) [§ 371(f)], applying to regulations embodying technical factual determinations, were simply intended to assure adequate judicial review of such agency decisions, and that their enactment does not manifest a congressional purpose to eliminate judicial review of other kinds of agency action." *Id.* at 144.

Judge Wilkey in his dissent, adopted the view that where the record for review is incomplete, as it is here, review must be before a district court which "*can develop the type of record . . . that the Food and Drug Act intended to be presented to the court of appeals.*" Slip op. at 40 (dissenting opinion), Appendix D at 58a. (Emphasis in original).

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[11] If the agency properly follows the procedures outlined in the statute, a proper factual record will exist for the court of appeals to review. The function of the district court in building that record will have been completed and the court of appeals may exercise its traditional function.

> "In summary, a reading of the *statutory language yields the conclusion that review in the court of appeals is premised on the existence of two conditions*: 1) a record which is 2) capable of being reviewed for *substantial evidence. If there is no record, or if it is such that cannot be meaningfully reviewed for substantial evidence, the implication is that the saving clause in § 701(f)(6) provides the remedy.*" Slip op. at 20 (dissenting opinion), Appendix D at 38a. (Emphasis in original).

Again:

> "It is clear from the legislative schemata and debate that the type of record developed in the ICMAD case here was envisioned as an appropriate record only when the factual basis on which the Commissioner proceeded went unchallenged.
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> "[*The*] *concern for the introduction of adverse evidence is a definite theme in the legislative history. There was no such testing of the evidence in this case.*" Slip op. at 30-31 (dissenting opinion), Appendix D at 48a-49a. (Emphasis in original).

In the proceedings before the Commissioner, petitioner set forth its objections to the proposed regulation and challenged the Commissioner to hold hearings to determine whether the proposed regulation was necessary to prevent the deception of consumers or to facilitate value comparisons as required by law.[12]

[12] Judge Wilkey describes the nature of petitioner's objections in his opinion. *See* Slip op. at 14-16 (dissenting opinion), Appendix D at 32a-34a. The majority of the court of appeals found most of these comments to be untimely and to be "petitions for amendment." However, as Judge Wilkey points out, the comments were filed prior to the time at which petitioner could reasonably have known what the regulations would in fact provide. Slip op. at 47 (dissenting opinion), Appendix D at 65a. Judge Wilkey called the majority's acceptance of the Commission's characterization of petitioner's objections as

> "a deplorable acquiescence in the Commissioner's deceitful effort to deny that what ICMAD filed were objections as called for by the statute, and to preclude judicial review by terming them petitions for amendment." Slip op. at 46 (dissenting opinion), Appendix D at 64a.

The Commissioner never did so and there exists no record in this regard. Judge Wilkey has aptly summarized the nature of the record:

> "There has been *no hearing* held during the period in which the regulation was promulgated. *There are no formal findings or conclusions presented by the Commissioner.* The evidence is presented straightforwardly, with *no reference to what the Commissioner found to be convincing or unconvincing.* Indeed, there is no overt indication that the Commissioner actually took any of the proffered information into account when promulgating the regulation.
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> "The Commissioner has admitted that the finding as to necessity is a factual matter. Even more significantly, the Commissioner has admitted that *he has evidence* to support a factual finding of necessity but *he refuses to put it in the record* because of his view that the objection was not timely filed. There was a similar objection filed earlier in the proceeding which prompted the Commissioner's defense of his finding of necessity on 17 October 1973, and the Commissioner failed to insert evidence at that time. The point is that this court is denied this vitally important information which is *admittedly* in the possession of the promulgating authority. *The court of appeals is asked to make substantial evidence determination on the basis of untested, unorganized, random, informal comments at the same time that*

that the Commissioner claims to have the type of evidence that the statute envisions to support his finding." Slip op. at 37-39 (dissenting opinion), Appendix D at 55a-57a. (Emphasis in original).

It was precisely for this reason that ICMAD invoked the savings clause contained in § 371(f)(6) and sought relief by declaratory judgment in the district court which "could elicit further facts . . . and therefore inject that element of adversariness envisioned in the statute and the legislative history"[13] which as the record shows had been sorely missing in the agency proceeding.

If this Court allows the court of appeals' holding that § 371(f)(1) vests "exclusive jurisdiction in the Court of Appeals" and at the same time allows that court's acceptance of the FDA's procedural convolutions to continue unchecked, the results are predictable and ominous. First, aggrieved parties such as ICMAD, which are not parties to the informal development of the regulations will be precluded from developing a record adequate for review by courts of appeal. Second, such parties will be precluded from seeking judicial review to develop such a record. Third, the FDA will continue to claim that its actions meet the Congressionally-mandated standard of necessity based on undisclosed assertions rather than on the basis of substantial evidence as required by law.

For the foregoing reasons, petitioner respectfully suggests that the holding of the court of appeals "has an importance far beyond its impact on this case." Slip op. at 2 (dissenting opinion), Appendix D at 20a.

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[13] Slip op. at 39 (dissenting opinion), Appendix D at 57a. (Emphasis omitted).

The court of appeals' disregard for the clear meaning of § 371(f) of the FFDCA, its legislative history, and this Court's ruling in *Abbott Laboratories* v. *Gardner* so far departs from the accepted and usual course of judicial proceedings as to call for an exercise of this Court's power of supervision. The importance of this case mandates that this Court grant the petition for writ of certiorari.

B. The Court of Appeals Erred in Holding That the FDA's Procedural Irregularities Did Not Prejudice ICMAD.

The decision of the court of appeals affirmatively sanctions numerous serious violations of the FFDCA, FPLA, APA, and FDA regulations by the Commissioner in promulgating the cosmetic ingredient labeling regulation. This Court must exercise its supervisory powers and overturn this harmful precedent.

In both its petition for review before the court of appeals and its complaint before the district court, ICMAD strenuously objected to the Commissioner's unjustified wholesale departure from statutorily-mandated procedures for promulgating the cosmetic ingredient labeling regulation. These departures severely prejudiced ICMAD not only because they effectively precluded ICMAD from participating in a meaningful manner in the promulgation of the regulation but also, as a result of the court of appeal's decision, now act to eclipse ICMAD's right to judicial review.

It is beyond peradventure that the Commissioner's actions contravened the requirements which Congress mandated for the promulgation of regulations governing cosmetic ingredient labeling. A comparison of the governing statutory provisions (Appendix G at 71a-72a) and the steps which the Commissioner took in

promulgating his regulation reveals a litany of procedural infirmities:

(a) The Commissioner did not "as soon as practicable" after October 17, 1973, publish a notice in the Federal Register specifying those parts of the October 17, 1973 order which had been stayed by objections, as required by 21 U.S.C. § 371(e)(2);

(b) The Commissioner did not hold a public hearing for the purpose of receiving evidence on the issues raised by the objections to the October 17, 1973 order, as required by 21 U.S.C. § 371(e)(3);

(c) The Commissioner held *ex parte* discussions with members of industry in an effort to resolve the objections and based his final order on these discussions rather than upon the statutorily-mandated hearing;

(d) The Commissioner made available on July 24, 1974, but did not publish, a "Tentative Revised Final Order" which is without basis in law and which served only to confuse interested parties as to the status of the October 17, 1973 order;

(e) The Commissioner issued, without previous publication as a proposal, his orders of March 3, 1975 which by his own admission amend the October 17, 1973 order;

(f) The Commissioner, without any published guidelines, and without ever having established his *prima facie* case, summarily overruled the majority of petitioner's objections to the March 3, 1975 order and denied petitioner a hearing on the issues raised by such objections;

(g) The Commissioner decreed that the October 17, 1973 order was "final agency action" with

regard to cosmetic ingredient labeling, although no reasonable person could have determined at that time that it would be so considered;

(h) The Commissioner failed to make the determination required by § 1454(c) of the FPLA that the regulation is "necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity";

(i) The Commissioner violated the express prohibition in § 1454(c)(3) of the FPLA that the ingredient labeling regulation not require that any trade secret be divulged.

The Commissioner's procedural violations seriously prejudiced ICMAD. The Commissioner's informal and *ad hoc* rulemaking precluded ICMAD from meaningfully participating in the promulgation process; ICMAD was denied its right to a hearing, was given no notice of stays imposed by the Commissioner or amendments to the regulation proposed by him, and its objection to the regulation were summarily dismissed after an unjustified delay. In addition, the convoluted and disjointed manner in which the regulation was promulgated created a "Catch-22" situation for ICMAD in which the Commissioner confounded ICMAD's attempts to obtain administrative due process. The impact of the Commissioner's deviations from required administrative procedure was not lost to Judge Wilkey:

> *"Thus, merely by delaying his response to objections, FDA has created a situation in which it can in effect insulate its actions from review by delaying its summary denial of objections.* The record of these proceedings is replete with such

> examples of the 'no-win' posture in which ICMAD has been placed by the combination of events that have taken place. I point to this one as merely being illustrative of the difficulties faced by ICMAD in dealing with the FDA's concept of administrative procedure." Slip op. at 45 (dissenting opinion), Appendix D at 63a. (Emphasis in original).

Fundamental principles of fair play and adherence to applicable procedural standards were conspicuously absent in the entire proceeding which culminated in the promulgation of the cosmetic ingredient labeling regulation. Violation of these principles and standards is the essence of prejudice in this case and the court of appeals should have so found.

C. The Court of Appeals Erred In Holding That ICMAD's Petition for Review was Untimely.

The record shows that ICMAD's petition for review in the court of appeals was filed on August 27, 1975, within ninety days of the May 30, 1975 publication of the FDA which was its final pronouncement on the matter of cosmetic ingredient labeling. As recognized by Judge Wilkey, May 30, 1975 was the first point in time at which ICMAD could "be certain that it would be 'adversely affected' in such a way as to justify and support a judicial challenge." Slip op. at 45-46 (dissenting opinion), Appendix D at 63a-64a.

The court of appeals refused to entertain ICMAD's petition for review on the ground that it was not filed within ninety days of October 17, 1973—the date which the Court found to be the date of final agency action subject to review. This decision rests upon the court's

approval of the "weird"[14] procedural steps employed by the Commissioner to circumvent the statutory requirements of § 371(e) of the FFDCA. The holding of the court of appeals as to the timeliness of ICMAD's petition for review presents a novel and important question of federal law which has not been, but should be, settled by this Court; that is, whether a federal agency should be allowed to preclude judicial review by promulgating regulations in a piecemeal fashion so that no part of the regulation is an identifiable final agency action.

As demonstrated above, the cosmetic ingredient labeling regulation was promulgated in a disjointed fashion from October 17, 1973 to May 30, 1975. During this period, the Commissioner endeavored to splinter the regulation into parts which he unilaterally and without justification denominated as "final orders." As Judge Wilkey notes, the Commissioner's actions in this regard apparently stemmed "from his desire to make as much of the regulation final as possible . . . and to *insulate the basic concept* from judicial review." Slip op. at 44 (dissenting opinion), Appendix D at 62a. (Emphasis supplied).

While the Commissioner designated his October 17, 1973 order a "Final Order", and the court of appeals held that ICMAD's petition for review should have been filed within ninety days of that date—the record is clear that the agency obviously was still working to finalize the regulation as it was ultimately issued on May 30, 1975 and is effective today. Subsequent to October 17, 1973, the agency (1) issued its "Tentative

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[14] Slip op. at 1 (dissenting opinion), Appendix D at 19a.

Revised Final Order" in July, 1974 (clearly the supposed final order of October 17, 1973 was not final in any real sense of that word, and indeed, the July 1974 Tentative Revised Final Order was subject to change since it was "Tentative"); (2) issued an entirely new set of amendments on March 3, 1975 which provided several alternative means of complying with the cosmetic ingredient labeling regulation (again, the introduction of alternatives shows that the October 17, 1973 order was not final); (3) issued still another final order on May 30, 1975 which summarily disposed of all but one of ICMAD's objections to the regulation and set a *new effective date* for the regulation. As Judge Wilkey stated, to imbue the Commissioner's October 17, 1973 order with administrative finality is an "administrative absurdity". Slip op. at 47 (dissenting opinion), Appendix D at 65a.

Whether an agency action is "final" for purposes of judicial review cannot be allowed to turn on what the agency chooses to call a particular act. The decision must rest on whether the agency action is such that (1) an aggrieved party is capable of determining whether and in what respect the action will impact him and (2) the agency action has reached a point in time where a reviewing court can scrutinize such action for compliance with statutory requirements. Clearly, October 17, 1973 was not that time. As recognized by Judge Wilkey, at that point in time, ICMAD was unable to determine if its members would be adversely affected. Moreover, if an appeal had been taken at that time, Judge Wilkey believes it would not have been accepted because the administrative proceeding was continuing and would not have been deemed ripe for

review under precedents of this Court.[18] The net effect of the court of appeals decision is to prevent ICMAD from ever obtaining a judicial review of the basic concept of cosmetic ingredient labeling—a concept which was not fully developed nor published until the Commissioner ceased issuing "final orders", "tentative revised final orders", and amendments to the regulation.

In sum, the import of the court of appeals decision is that "it has given support to the most desperate efforts of the Commissioner to avoid judicial review at all costs." Slip op. at 46 (dissenting opinion), Appendix D at 64a. The majority's decision ignores fundamental notions of due process and sets a dangerous precedent which in effect requires all persons aggrieved by future agency actions to file petitions for review from every so-called "final order" of every administrative agency, regardless of whether the agency has completed its action. Petitioner respectfully requests this Court not to allow the court of appeals' decision to stand.

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[18] *See e.g. Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967); *Port of Boston Maine Terminal Ass'n.* v. *Rederiaktiebolaget Transatlantic*, 400 U.S. 62 (1970).

VII. CONCLUSION

The decision below is in conflict with principles established in applicable decisions of this Court and involves important questions of federal law. Furthermore, the court below has so far departed from the accepted and usual course of judicial proceedings as to call for an exercise of this Court's power of supervision. The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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Counsel for Petitioner.

APPENDIX

APPENDIX A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1413

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Plaintiff*,

v.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare; ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs; and THE UNITED STATES OF AMERICA, *Defendants.*

Order

(Filed October 21, 1975)

Upon consideration of the motion of the plaintiff for summary judgment and the motion of the defendants to dismiss or for summary judgment, the points and authorities in support thereof and the argument of counsel, and it appearing to the Court that it does not have jurisdiction over the subject matter of this action, it is by the Court this 20th day of October, 1975,

ORDERED that the cross motions for summary judgment are denied and defendants' motion to dismiss is granted and that this action be and it hereby is dismissed.

/s/ JOSEPH L. WADDY
United States District Judge

Presented by:

/s/ A. PATRICIA FROHMAN
A. Patricia Frohman
Assistant United States Attorney
U.S. District Courthouse
Room 3437
426-7353

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1007

September Term, 1976

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Appellant*

v.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare, et al

Appeal from the United States District Court for the District of Columbia.

Before: ROBB and WILKEY, *Circuit Judges* and GESELL,* *United States District Judge for the District Court of the District of Columbia.*

Judgment

(Filed January 27, 1977)

THIS CAUSE came on to be heard on the record on appeal from the United States District Court for the District of Columbia, and was argued by counsel.

ON CONSIDERATION THEREOF It is ordered and adjudged by this Court that the judgment of the District Court appealed from in this cause is hereby affirmed.

Per Curiam

For the Court
/s/ GEORGE A. FISHER
George A. Fisher
Clerk

Opinion will follow at a later date.

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* Sitting by designation pursuant to 28 U.S.C. § 292(a).

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 75-1845

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Petitioner*

v.

UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE;

UNITED STATES FOOD AND DRUG ADMINISTRATION, ALEXANDER MCKAY SCHMIDT, Commissioner of Food and Drug Administration, *Respondents*

PETITION FOR REVIEW OF AN ORDER OF THE FOOD AND DRUG ADMINISTRATION

Before: ROBB and WILKEY, *Circuit Judges* and GESELL,* *United States District Judge for the District Court of the District of Columbia.*

Judgment

(Filed January 27, 1977)

This cause came on to be heard on a petition for review of an order of the Food and Drug Administration and was argued by counsel. On consideration of the foregoing, it is

ORDERED AND ADJUDGED by this Court that the petition for review herein is denied.

Per Curiam

For the Court
/s/ GEORGE A. FISHER
George A. Fisher
Clerk

Opinion will follow at a later date.

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* Sitting by designation pursuant to 28 U.S.C. § 292(a).

APPENDIX D

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 75-1845

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

UNITED STATES FOOD AND DRUG ADMINISTRATION, DONALD KENNEDY, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION, RESPONDENTS

Petition for Review of an Order of the Food and Drug Administration

No. 76-1007

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., APPELLANT

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

D

Appeal from the United States District Court for the District of Columbia

(D.C. Civil 75-1413)

Argued December 14, 1976

Decided February 13, 1978

Walter E. Byerley for petitioner/appellant.

John R. Fleder, Attorney, Department of Justice, with whom *Charles R. McConachie*, Chief, Consumer Affairs Section and *Robert V. Allen*, Attorney, Department of Justice, were on the brief for respondent/appellee, Health, Education and Welfare.

Donald Beers, United States Food and Drug Administration, with whom *Richard A. Merrill*, Chief Counsel, United States Food and Drug Administration were on the brief for respondent Food and Drug Administration.

Before: ROBB and WILKEY, *Circuit Judges*, and GESELL,* *United States District Judge* for the United States District Court for the District of Columbia

Opinion for the court filed by *Circuit Judge* ROBB.

Dissenting opinion filed by *Circuit Judge* WILKEY.

ROBB, *Circuit Judge*: Independent Cosmetic Manufacturers and Distributors, Incorporated (ICMAD) challenges a regulation promulgated by the Food and Drug Administration. The regulation requires that all packaged cosmetics be identified by labels listing their ingredients. ICMAD challenged the regulation on two fronts. First, ICMAD sought declaratory and injunctive relief in the District Court. The District Court dismissed the suit for want of jurisdiction and ICMAD appeals.

* Sitting by designation pursuant to 28 U.S.C. § 292(a).

ICMAD's second front is a petition in this court for direct review of the regulation.

We affirm the District Court's holding that it lacked jurisdiction, for jurisdiction lies exclusively in the court of appeals. In exercising our jurisdiction, however, we decline to set aside the regulation. We turn first to the jurisdictional issue.

Jurisdiction of the District Court

The regulation may be challenged by petition to an appropriate United States Court of Appeals. 15 U.S.C. § 1455(a); 21 U.S.C. § 371(f). The statute does not specify whether district courts may exercise concurrent jurisdiction when an independent source of jurisdiction can be found. ICMAD asserts, however, that the trial court had concurrent jurisdiction by virtue of a savings clause in the statute, 21 U.S.C. § 371(f)(6). That clause provides:

> The remedies provided for in this subsection [review in the court of appeals] shall be in addition to and not in substitution for any other remedies provided by law.

We think jurisdiction in this case is governed by our decision in *Nader v. Volpe*, 151 U.S. App. D.C. 90, 466 F.2d 261 (1972). In that case we considered a similar review provision of the National Traffic Motor Vehicle Safety Act, with an almost identical savings clause. *See* 15 U.S.C. § 1394(a). We concluded that when Congress has specified a procedure for judicial review of administrative action, that procedure is the exclusive means of review unless, because of some extraordinary circumstances, the procedure fails to provide an adequate remedy. 151 U.S. App. D.C. at 100, 466 F.2d at 271. Those extraordinary circumstances, we noted, were "instances of agency action which is *ultra vires* or damaging beyond the capability of the statutory procedure to repair." *Id.*

Although ICMAD contends that the Commissioner's action in this case is *ultra vires*, we disagree. As our opinion in *Nader v. Volpe* makes clear, a party urging jurisdiction based on *ultra vires* action must show a patent violation of agency authority. *Compare* 151 U.S. App. D.C. at 100 & n.66, 466 F.2d at 271 & n.66, *with* 151 U.S. App. D.C. at 95 & n.30, 466 F.2d at 266 & n.30. ICMAD argues that the agency disregarded 15 U.S.C. § 371(e)(3) in failing to hold a hearing "as soon as practicable" after objections were filed regarding certain parts of the regulation promulgated on October 17, 1973. The objections—none of which came from ICMAD—asserted that exemptions to labeling and alternative means of compliance should be permitted. Instead of immediately convening a hearing the Commissioner began negotiations with the objectors. This informal procedure was, at least in part, invited by the objectors.[1] The negotiations resulted in the amendment of the regulation on March 3, 1975 (40 Fed. Reg. 8918), after which the objections were withdrawn and the need for a hearing obviated. 40 Fed. Reg. 23460 (1975). We need not determine whether upon closer scrutiny this informal procedure fully comported with the statute; it is sufficient that we decide that in these circumstances the failure to hold a hearing was not a patent violation of agency authority. Nor are any of the lesser irregularities alleged by ICMAD so patently defective as to warrant district court jurisdiction.

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[1] The Cosmetic, Toiletry and Fragrance Association (CTFA) was the major party objecting to the parts of the regulation. CTFA included with its objection a proposed amendment to the regulation and stated that if adopted the amendment would remove the basis for its objections and the need for a hearing. Letter from CTFA to the Dept. of HEW, Nov. 16, 1973. In addition, CTFA subsequently wrote the Commissioner reiterating that adoption of the proposed amendments was intended to be an alternative to holding a hearing on CTFA's objections. Letter from CTFA to the Associate Commissioner for Compliance, FDA, May 15, 1974.

Our conclusion is consistent with settled principles of law[2] and the legislative history of the Food and Drug Act.[3] ICMAD contends, however, that the legislative history as set out in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), is contrary to our conclusion and that the Court's holding there controls this case. We disagree. The Supreme Court in the *Abbott Laboratories* case noted that Congress intended in enacting the savings clause to preserve, not concurrent jurisdiction, but equitable remedies available when no adequate remedy at law exists. *See id.* at 142-43. The Supreme Court did uphold district court jurisdiction in that case, for no special statutory review provisions applied to the challenged regulations, *id.* at 141, and hence there was no adequate remedy at

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[2] "[I]t is well settled that bifurcated jurisdiction between District Court and Court of Appeals over identical litigation is not favored." Oljato Chapter of Navajo Tribe v. Train, 169 U.S. App. D.C. 195, 201, 515 F.2d 654, 660 (1975). And, as we noted in Investment Company Institute v. Board of Governors, 551 F.2d 1270, 1279-80 (1977):

> Indeed, an impressive line of authority supports the . . . proposition that, even where Congress has not expressly conferred exclusive jurisdiction, a special review statute vesting jurisdiction in a particular court cuts off other courts' original jurisdiction in all cases covered by the special statute. *See, e.g., Macauley v. Waterman S.S. Corp.*, 327 U.S. 540, 543-545 (1946); *E. I. duPont de Nemours & Co. v. Train*, 528 F.2d 1136, 1137 & n.1, 1142 (4th Cir. 1975), [*aff'd in part* 45 U.S.L.W. 4212 (1977)]; *UMC Industries, Inc. v. Seaborg*, 439 F.2d 953, 955 (9th Cir. 1971); *United States v. Southern Ry. Co.*, 380 F.2d 49, 53-54 (5th Cir. 1967)....

To this line of authority supporting our position must be added our opinion in the *Investment Company* case, as well as recent circuit opinions in Virginia Electric and Power Co. v. Costle, No. 76-2081 (4th Cir. Nov. 11, 1977), and U.S. Steel Corp. v. Train, 556 F.2d 822, 837 (7th Cir. 1977).

[3] *See* note 4, *infra*.

law. *Nader v. Volpe*, 151 U.S. App. D.C. at 100 n.68, 466 F.2d at 271 n.68 (distinguishing *Abbott Laboratories v. Gardner* on this basis). Indeed, the Supreme Court said in the *Abbott Laboratories* opinion, "when the special provisions [for review] apply, presumably they must be used and a court would not grant injunctive or declaratory relief unless the administrative procedure is exhausted." *Id.* at 146; *see Katzenbach v. McClung*, 379 U.S. 294, 296 (1964). Here those special procedures for review do apply and as we noted in *Nader v. Volpe*:

> The District Court had but limited jurisdiction of the case at the outset—for the purpose of taking a peek to see whether it had jurisdiction of the subject matter by virtue of exceptional circumstances. When it found no such circumstances it rightly dismissed the action for lack of subject-matter jurisdiction.

151 U.S. App. D.C. at 101, 466 F.2d at 272.

That exclusive jurisdiction lies in the courts of appeals is further demonstrated by the scheme of the Act. Finding concurrent jurisdiction under some general jurisdictional mandate, such as federal question jurisdiction, would permit ICMAD to bypass the 90-day time limit that Congress imposed on petitions to review challenged regulations. *See* 21 U.S.C. § 371(f)(1). That is precisely what ICMAD seeks to do here; for as we demonstrate later, a major portion of ICMAD's petition for direct review in this court is untimely.[4]

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[4] Moreover, the comprehensiveness of our review power is evinced by the statutory review provision permitting the administrative record to be supplemented upon petition to the courts of appeals. Section 371(f)(2) of the statute, regarding petitions for review to the courts of appeals, provides:

> If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure

> to adduce such evidence in the proceeding before the Secretary, *the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary*, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

21 U.S.C. § 371(f)(2) [emphasis added]. Thus, the Act clearly envisions that the courts of appeals should have jurisdiction of cases in which the administrative record is deficient.

The dissent reads the quoted statutory provision, however, to reach the conclusion that when the record is inadequate, trial before the District Court is mandated. Dissent at 19-20. We disagree. The dissent's conclusion disregards the clear import of section 371(f)(2). Further, subjecting the Commissioner's regulations to a trial *de novo* in the District Court would be inimical to the aim of Congress in enacting section 371(f). Indeed, several congressmen urged that the statute provide for trial *de novo* in the district courts, but the idea was rejected for fear that harassing suits in that forum would "hamstring" the Commissioner. Abbott Laboratories v. Gardner, 387 U.S. 136, 143 (1967); *compare* 83 CONG. REC. 7779, 7785-86, 7789 (1938) *with* H.R. REP. No. 2139, 75th Cong., 3d Sess. 10-13 (1938). Instead, review in the courts of appeals was adopted as "a method of reviewing agency *factual* determinations." Abbott Laboratories v. Gardner, 387 U.S. 136, 143 [emphasis in original]. To order a trial *de novo* in the District Court would therefore appear to violate Congress' intent as well as to ignore section 371(f)(2). *See* Investment Company Institute v. Board of Governors, 551 F.2d 1270, 1279 (D.C. Cir. 1977).

ICMAD's challenges here appear not to be based on any factual dispute but are premised on the Commissioner's exceeding his authority under the statutes. *See* ICMAD's complaint at 7-9, J.A. at 8-10; Brief of Petitioner ICMAD at 12-21. These challenges are outlined in that portion of our opinion discussing ICMAD's petition for review.

The dissent appears to say that a factual issue was raised by ICMAD's contention that the Commissioner made *no* determination that the regulation was necessary to prevent the deception of consumers or to facilitate value comparisons. ICMAD's argument however is, as stated in its brief, a nonfactual one:

> It is beyond dispute that the Commissioner failed to make the statutory finding that the ingredient labeling regulation is necessary to prevent deception or to facilitate value comparisons. Instead, he stated in conclusory language that ingredient labeling "can be meaningful" in preventing consumer deception and that ingredient identity "is one important criterion of a product's value. . . ." (38 Fed. Reg. 28912 (Oct. 17, 1973)). That a regulation "can be meaningful," or that ingredient identity is an "important criterion of a product's value" does not demonstrate that uniform cosmetic ingredient labeling is "necessary" to prevent deception or facilitate value comparisons. Since there has been no finding of necessity, the regulation must be held unlawful as contrary to § 1454(c) of the FPLA.

Appellant ICMAD's Brief in No. 76-1007 at 28-29; *see* Petitioner ICMAD's Brief in No. 75-1845 at 13-15.

Indeed, as the dissent notes, the Commissioner does not contend before this court that he compiled a record in making the necessary determination; rather, the Commissioner argues that the determination was made and that the Act does not require a completed administrative record unless a party timely objects to the determination, which no party did. Respondents' Brief at 9-11. Thus, the only question regarding the record is the purely legal one of whether the Commissioner was correct in not compiling a record.

We note for clarification that the statute supports the Commissioner's reasoning. The Act requires that the Commissioner make findings of fact, which are to be based on substantial evidence, only after a public hearing has been held, 21 U.S.C. § 371(e)(3), and the Act mandates a public hearing only after a party objects to an order and requests a hearing, *id.* (2), (3). Moreover, the scope of the hearing is to consider only issues raised by the objections, *id.* (3), and thus the record and findings must relate to only those issues. ICMAD made no timely request, and the requests by others for a hearing on matters unrelated to ICMAD's claims here were withdrawn. Nor does the absence of an administrative record imply that

PETITION FOR REVIEW

In its petition to this court ICMAD challenges the Commissioner's regulation in two respects. First, on several different theories ICMAD argues that the substance of the original regulation contravenes the Fair Packaging and Labeling Act (F.P.L.A.). *See* Petitioner's Brief in 75-1845 at p. 3. Second, ICMAD contends that the procedure followed by the Commissioner in promulgating amendments to the regulation was deficient. *Id.* Because ICMAD's challenge to the original regulation is untimely and because ICMAD has not been prejudiced by the procedure followed in adopting the amendments, we deny its petition.

ICMAD argues that the cosmetic ingredient labeling regulation violates the F.P.L.A. because: section 1454 of the Act mandates that the Commissioner promulgate labeling regulations on a commodity-by-commodity, not a cosmetic-wide, basis; that the Commissioner, contrary to section 1454(c), made no determination that the regulation was necessary to prevent deception and to facilitate comparisons;[4] that contrary to section 1454(c)(3) the regulation requires divulgence of trade secrets; and that while section 1454(c)(3) requires labeling of only certain ingredients, the regulation requires labeling of all ingredients. *See* Petitioner's Brief at 13-23.

ICMAD's attack challenges the original regulation, which was published in final form in the Federal Register

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this court is an improper forum for review; were the issue properly presented, we could review the Commissioner's basis for determining that the regulation was necessary. *See* Mobil Oil Corp. v. FPC, 152 U.S. App. D.C. 119, 469 F.2d 130 (1972); Kennecott Copper Corp. v. EPA, 149 U.S. App. D.C. 231, 462 F.2d 846 (1972); *see also* City of Chicago v. FPC, 147 U.S. App. D.C. 312, 322 n.45, 458 F.2d 731, 741 n.45 (1971).

[4] *See* note 4, *supra*.

on October 17, 1973 (38 Fed. Reg. 28912).[5] Section 371

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[5] The dissent poses the questions, "Where, When, and from What judicial review should take place." We decide in the first part of this opinion that as to "Where", the proper forum is the courts of appeals. With respect to "When", the statute compels that the request for review be within 90 days of the date of the order that adversely affects the petitioning party. The "What" in this case is the October 17, 1973 order, which promulgated the basic regulation.

The dissent asserts, however, that the order of October 17, 1973 served primarily only as an expression of the Commissioner's view on comments received regarding the regulation and as an opportunity to invite formal objections and requests for hearing. Dissent at 8. Because the order invited formal objections and hearing requests, the dissent surmises that "the form and content of the regulation were still very much open to discussion and debate."

The dissent in elaborating the effect of the October 17, 1973 order, however, ignores its principal function: to promulgate in final form the earlier proposed regulation. Thus, after discussing the comments received on the proposal, the Commissioner announced:

> The Commissioner concludes that all cosmetic labeling ordered after March 31, 1974, and all cosmetic products labeled after March 31, 1975, shall comply with this regulation. This will, within reasonable limits, allow industry time to exhaust current inventories, redesign labeling, and obtain new labeling.
>
> Therefore, pursuant to provisions of the Fair Packaging and Labeling Act (secs. 5(c), 6(a), 80 Stat. 1298, 1299; 15 U.S.C. 1454, 1455) and the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055-1056, as amended; 21 U.S.C. 371(e)), and under authority delegated to the Commissioner (21 CFR 2.120), Part 1 is amended by adding the following new section:
>
> * * * *

38 Fed. Reg. 28913. This pronouncement was followed by a statement of the regulation in the form customarily used by agencies when promulgating regulations in the Federal Register.

Furthermore, the Commissioner's inclusion in the order of a statement of the parties' rights to object and request a

(f) (1) of the Food and Drug Act requires that petitions for review of an FDA order be filed within 90 days from the date the order issues, and ICMAD's petition for review in 1975 clearly falls outside that 90-day boundary. Nor can ICMAD's challenge be deemed timely filed as an attack on the amendments promulgated in 1975. The amendments merely provided narrow exemptions to labeling and alternate means of compliance applicable in limited circumstances.[7] A comparison of the original regulation and the amendments makes clear that the amendments did not change the substance or thrust of the origi-

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hearing does not suggest that the order was not appealable. The Act permits review of an order acting upon a proposed regulation that has been publicized and commented on. 21 U.S.C. § 371(f) (1). The October 17, 1973 order was such an order. ICMAD could therefore petition for review of this order, or alternatively, it could object to the order and seek a hearing. 21 U.S.C. § 371(e) (2). Therefore, inclusion of a statement of this right, granted by statute, should not make an otherwise appealable final order something else.

Nor do we believe that the subsequent amendments so altered the character of the original regulation that the regulation must be deemed not to have been in final form until after promulgation of the amendments. While the dissent appears to measure the effect of the amendments on the regulation spatially, we believe a less quantitative gauge is required. Our reading of the two sections shows that the amendments only granted limited exemptions and alternate means of compliance and thus they did not alter the fundamental character of the original regulation, which went into effect October 17, 1973. For example, the first section of the amendments permits manufacturers a slight variance from the requirement in the basic regulation that ingredients be listed in descending order of predominance. It permits grouping without respect to predominance of color additives and of ingredients, other than color additives, which are present at a concentration of not more than one percent. 40 Fed. Reg. 8922 (1975).

[7] *See* note 6, *supra*.

nal regulation. *See* 40 Fed. Reg. 8918-24 (1975); note 6, *supra*. The attack on the original regulation is therefore untimely.

ICMAD's procedural attack must also fail. ICMAD urges that because of alleged irregularities in amending the regulation, it was foreclosed from challenging the basic regulation. We believe however that if any irregularity occurred, ICMAD was not prejudiced thereby and hence no basis exists for setting aside the original regulation.

A brief review of the history of the challenged regulation is helpful in analyzing ICMAD's procedural contention. The regulation was promulgated on October 17, 1973. 38 Fed. Reg. 28912. Within the 30-day period permitted by the statute, several parties objected to certain parts of the regulation and requested a hearing. *See* 21 U.S.C. § 371(e) (2). ICMAD neither objected nor requested a hearing during this 30-day period;[8] and those parties objecting merely sought narrow exemptions and alternate compliance methods. *See* 40 Fed. Reg. 8918-21 (1975). The objections stayed the effectiveness of the parts of the regulation objected to, but only those parts. *See* 21 U.S.C. § 371(e) (2). And, as we have said, any party seeking to challenge the other parts in the courts had only ninety days from the date of the order to file its petition. This ICMAD also failed to do. At the close of the 30-day period for objecting, the Commission began negotiations with the objectors. As a result the objections were withdrawn and no hearing was held. Apparently because of these negotiations, the Commissioner did not publish a notice of what parts of the regulation were stayed until sixteen months after the objections were filed,

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[8] Therefore, contrary to the implication of the dissent, ICMAD was not denied the opportunity for a hearing on its challenge to the basic regulation; rather, ICMAD waived its statutory right to such a hearing by failing to make a timely request.

although the Act requires notice as soon as practicable after the close of the 30-day period for objecting. *See id.*

ICMAD contends that this procedure precluded it from contesting the original statute. It argues, more specifically, that it was denied a hearing to contest the legality of labeling when the Commissioner failed to hold a hearing on the timely filed objections. As we have pointed out, even if a hearing was required, the purpose of the hearing would only have been to consider and receive evidence on the objections, which raised issues unrelated to ICMAD's claims here. Thus, the absence of a hearing did not prejudice ICMAD in its challenge to the basic regulation and therefore that cannot be a basis for overturning the regulation. *See Braniff Airways, Inc. v. CAB*, 126 U.S. App. D.C. 399, 413, 379 F.2d 453, 465 (1967).

Similarly, ICMAD's challenge to labeling could not have been prejudiced by the Commissioner's failure on July 25, 1974 and March 3, 1975 to publish the proposed amendments.[9] Those amendments, we have noted, provided exemptions and alternate means of compliance, an approach that ICMAD apparently endorses.[10] The amendments had nothing to do with the claims that ICMAD now makes

[9] On July 25, 1974 the Commissioner, instead of publishing the proposed amendments, gave public notice that a tentative revised final order reflecting the proposal was available. 39 Fed. Reg. 27181. The notice also invited comment by interested parties. On March 3, 1975 the Commissioner published the amendments in final form. 40 Fed. Reg. 8918.

[10] By letter of April 1, 1975 ICMAD commented on the amendments. Except for contesting the original regulation, an attack the Commissioner found untimely (40 Fed. Reg. 23158, 23159 (1975)), ICMAD principally argued for additional exemptions and alternate means of compliance. As the Commissioner concluded, this argument properly should be styled a request for further amendments and not an objection to the present amendments. 40 Fed. Reg. 23159.

before this court. Moreover, the alleged omissions occurred well after the requirement of labeling had become final and ICMAD had lost its right to object and petition for review.

ICMAD's most forceful procedural argument is that it was prejudiced by the Commissioner's failure to publish promptly a notice of stay. 15 U.S.C. § 371(e)(2) mandates that "as soon as practicable" a notice shall be published "specifying those parts of the order which have been stayed by the filing of objections . . . ." The Commissioner filed no notice of stay until some 16 months after objections had been filed. 40 Fed. Reg. 8918 (1975). ICMAD contends that had a notice of stay been filed, it would have known that no one had objected to the concept of labeling and accordingly it might have filed a timely petition for review.

We cannot agree however that ICMAD was prejudiced. The statute does not make publication of a notice of stay a prerequisite for seeking judicial review. Rather, the statute clearly specifies that a petition for review must follow within ninety days of the order. 21 U.S.C. § 371(f)(1). ICMAD does not, and could not, contend that the lack of a notice misled it into believing that its challenge had somehow been mooted by objections.[11] No prejudice is thus apparent. Indeed, what ICMAD actually seeks is to have us amend section 371(f) to extend the time for filing a petition for review until after publication of a notice of stay. This is a legislative task which we decline.

[11] In fact, the Commissioner adopted many of the proposals advanced by the objectors, *see* 40 Fed. Reg. 8918-21 (1975), and had the Commissioner adopted all the objectors' proposals, *see id.*, it is difficult to understand how that would have mooted any of ICMAD's contentions.

CONCLUSION

We affirm in No. 76-1007 the District Court's dismissal for lack of jurisdiction. Jurisdiction in this case lies exclusively in the court of appeals. We deny, in No. 75-1845, ICMAD's petition for review. The challenge to the substance of the 1973 regulation is untimely; the attack on the procedure followed in amending that regulation fails because no prejudice has been shown.

So Ordered.

WILKEY, *Circuit Judge*, dissenting: The majority here achieves a remarkable result: the petitioner is denied relief in the District Court because the Court of Appeals has exclusive jurisdiction; the petitioner is denied relief in this Court of Appeals because petitioner's challenge is "untimely"; even though it was precisely the weird procedure in the FDA which left the petitioner with neither clear reason nor opportunity to challenge the regulations, "the attack on the procedure . . . fails because no prejudice has been shown"; and, by lifting of the protective stay on 14 March 1977 with the reasons for decision following eleven months later, the petitioner has been denied any realistic chance of relief by seeking en banc consideration or certiorari. How did Justice assume this shape??

It is significant that there is not a Statement of Facts as such in the majority opinion; rather, highlights of the procedural history are interspersed through a discussion of legal precedents. The procedural facts here are detailed and all important to a correct appreciation and resolution of a jurisdictional conundrum which is being posed with increasing frequency to this court. In this particular matter the procedural history is embarrassing to the FDA and to the disposition the majority make of this case. If the reader receives the impression that the Commissioner was operating without legal counsel, or with lawyers who preferred to ignore the agency's basic statute and the Administrative Procedure Act, while devising *ad hoc* procedure en route to final regulations, that impression is an accurate reflection of the record.

For any effective analysis of both the specific errors here and the recurring legal problem, no giant slalom through the facts, touching a pole here and there, will suffice. We must first look very carefully at the procedural steps taken by the Commissioner and the appropriateness of the responsive action (or non-action) taken by the petitioner, before proceeding to an analysis of Where, When

and from What judicial review should take place. The Where, When, and What of judicial review under these circumstances has, in my opinion, an importance far beyond its impact on this case; the *ad hoc* procedure blithely employed by the FDA here serves only as a glaring illustration of why careful, thorough consideration by this court is necessary.

In these two cases the Independent Cosmetic Manufacturers and Distributors, Inc. (ICMAD), a trade association comprised of small-to-medium sized manufacturers and distributors of cosmetic, skin care, and fragrance products, seeks to challenge a cosmetic ingredient labeling regulation [1] promulgated by the Commissioner of the Food and Drug Administration pursuant to § 1454 of the Fair Packaging and Labeling Act (FPLA).[2] Recognizing confusion in the law regarding the proper forum for judicial review,[3] ICMAD filed suit in the District Court for de-

[1] 21 C.F.R. § 701.3.

[2] 15 U.S.C. § 1454.

[3] "The only lawyer-like remedy today, as Judge McGowan points out, is double filing." *Investment Co. Institute* v. *Board of Governors of the Federal Reserve Sys.*, 551 F.2d 1270 at 1283 (D.C. Cir. 1977) (Leventhal, J., concurring); *Cf*: Ingraham, J. in *Lo-Vaca Gathering Co.* v. *Railroad Comm'n of Texas*, (TECA, 19 Oct. 1977, slip op. 9), ". . . there is only an original complaint before this court, and . . . no record exists from which an appellate argument can be made. Lo-Vaca would fill this void by transforming TECA into a trial level court to receive evidence and develop facts. . . . We realize that Congress has extended our jurisdiction by cutting out the district court to provide direct review of agency action. We do not believe, however, that it was the intent of Congress to convert TECA into a trial level court. . . ."; and Wright, J. (dissenting in part) in *National Resources Defense Council* v. *Environmental Protection Agency*, 512 F.2d 1351, 1361 (D.C. Cir. 1975) ". . . the courts play jurisdictional badminton with these provisions" between the district court and court of appeals. *See: Lubrizol Corp.* v. *Environmental Protection*

claratory and injunctive relief on 27 August 1975; *on the same day*, ICMAD filed a petition for review of the regulation in this court. The result of the majority's decision on both of petitioner's pleas is to *deny* ICMAD *any opportunity* to obtain judicial review of the Commissioner's cosmetic labeling regulation *anywhere*.

I dissent from the majority's position on the grounds that the District Court has subject matter jurisdiction over ICMAD's action and that, in the context of this case, the District Court was the proper forum for ICMAD's challenge. Most emphatically, I also dissent from the majority's conclusion that ICMAD's petition in this court was not timely filed. These cases present a significant and recurring issue related to the choice of the proper federal forum in which to mount a challenge to federal administrative agency action; *the result here is that federal agency action is totally insulated from judicial review.*

I. The Agency Proceedings

The thesis of this dissent is that *the nature of the administrative record is central to a determination as to the proper forum* in this and similar cases; the procedural history of the labeling regulation emphasizes this critical point as to the nature of the record which has been developed.

In addition, the precise chronology of events is crucial to making an informed decision on the question of the *timeliness* of ICMAD's petition in this court. In this part, I shall first outline the statutory authority under which the Commissioner proceeded in promulgating the regulation, and then proceed to examine in detail the various stages in the evolution of the cosmetic labeling regulation.

Agency, 562 F.2d 807, note 19 at 813 (D.C. Cir. 1977); *Utah Power & Light Co.* v. *Environmental Protection Agency*, 553 F.2d 215, note 20 at 219, (D.C. Cir. 1977); *Natural Resources Defense Council* v. *Train*, 519 F.2d 287, 291 (D.C. Cir. 1975).

A. *Statutory Authority*

Section 1454(c) of the FPLA grants the Secretary of Health, Education and Welfare the discretionary authority to promulgate labeling and packaging regulations whenever he determines such regulations "are necessary to prevent the deception of consumers or to facilitate value comparisons."[4] This authority may be exercised to require, among other things, "that the label on each package of a consumer commodity . . . bear (a) the common or usual name of such consumer commodity, if any, and (b) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance," so long as trade secrets are not required to be divulged.[5] The labeling regulation at issue in these cases seeks to prescribe the precise method to govern such a listing of cosmetic ingredients in order of decreasing predominance.

In promulgating labeling regulations, the Secretary is required by § 1455 of the FPLA to observe the procedural requirements of section 701(e) of the Federal Food, Drug and Cosmetic Act.[6] Also, the judicial review of these regulations is governed by the provisions of section 701(f) of the Food and Drug Act.[7] Therefore, in analyzing the issues presented in this case, the provisions of the Food and Drug Act, not the FPLA, will be the primary focus of concern.

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[4] 15 U.S.C. § 1454(c).

[5] *Id.*

[6] 15 U.S.C. § 1455(c). Section 701(e) of the Food, Drug and Cosmetic Act is codified at 21 U.S.C. § 371(e). Throughout this opinion reference will be made to the sections of the Act as enacted, with footnote references to the U.S. Code citations where appropriate.

[7] *Id.*

B. *Procedural Background.*

The central point to be kept in mind is that the cosmetic ingredient labeling regulation was promulgated in an amazingly piecemeal fashion during the period beginning 7 February 1973 and ending 30 May 1975. During this period the Commissioner published notices and other material concerning the regulation on five separate occasions in the Federal Register,[8] and took other action not so noticed. The undeniable result was, contrary to the majority opinion, that the petitioner had not clear designation as to from What it should appeal, When, and eventually, Where! For purposes of organizing this discussion of the procedural background, these five communications from the Commissioner will be examined *seriatim.*

1. *7 February 1973.* On this date the Commissioner first issued the proposal for the labeling of cosmetics. There were actually two proposals put forth in this notice —one proposal consisted of a petition presented by a private party, while the other was the Commissioner's pro-

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[8] The five Federal Register Notices are as follows:

(1) 7 February 1973—*Notice of Proposed Rulemaking,* 38 Fed. Reg. 3523-25.

(2) 17 October 1973—*Cosmetic Ingredient Labeling,* 38 Fed. Reg. 28912-14.

(3) 25 July 1974—*Notice of Availability of Tentative Revised Final Order,* 39 Fed. Reg. 27181.

(4) 3 March 1975—There were two Notices published Thursday:

(A) *Cosmetic Labeling: Designation of Ingredients on Package Labels,* 40 Fed. Reg. 8918-24;

(B) *Cosmetic Labeling: Designation of Ingredients; Confirmation of Effective Date and Stay of Certain Provisions,* 48 Fed. Reg. 8924-26.

(5) 30 May 1975—*Final Order, Cosmetic Labeling,* 40 Fed. Reg. 23458-60.

posal. The Commissioner's proposal is the one which was subsequently discussed, amended, and adopted, and any further mention of the labeling regulation will refer to this proposal. The Commissioner's proposal sought to add § 1.205 to Chapter I of 21 C.F.R. and, at this time, consisted of *four* subsections.

In the notice of 7 February 1973 the Commissioner stated that written comments on the proposal to require ingredient labeling would be received until 9 April 1973.

2. *17 October 1973.* In this notice the Commissioner announced that 291 comments had been received in response to the proposals published on 7 February 1973. Several comments received during this period questioned (1) the Commissioner's legal authority to promulgate the regulation and also questioned (2) whether the Commissioner had met the *statutory standard* of determining that the regulation was necessary to prevent consumer deception or to facilitate value comparison. These objections are of great importance in this case because they later formed the basis for ICMAD's judicial challenge to the regulation.

The Commissioner undertook to answer these two objections in the notice of 17 October 1973. With respect to the statutory authority issue, the Commissioner stated:

> The Commissioner concludes that Section 5 of the Fair Packaging and Labeling Act contains ample authority for the promulgation of this regulation. For the purposes of ingredient labeling, the Commissioner concludes that all cosmetics are appropriately considered a single "commodity". However, even if the term "cosmetic" is considered to encompass several separable cosmetic "commodities", nevertheless the Commissioner concludes that ingredient labeling is needed for all such commodities and that a comprehensive order governing all such commodities in this respect is most efficient. As the United

> States Supreme Court has recently observed in upholding other regulations of the Food and Drug Administration, "[t]he comprehensive rather than the individual treatment may indeed be necessary for quick effective relief." *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 93 S.Ct. 2469, 2481 (June 18, 1973).[9]

With respect to the statutorily mandated finding of necessity, the following justification was put forth:

> The Commissioner also concludes that cosmetic ingredient labeling is necessary to prevent the deception of consumers and to facilitate value comparisons. Ingredient labeling can be meaningful in preventing consumer deception by precluding product claims that are unreasonable in relation to the ingredients present and by providing consumers with additional information that can contribute to a knowledgeable judgment regarding the reasonableness of the price of the product. Furthermore, while ingredient identity may not be the sole determinant of a product's value to a consumer, it is one important criterion of a product's value in comparison with others. The presence of a substance to which a consumer is allergic or sensitive, for example, may render the product worthless to that consumer.[10]

In the entire record of the proceedings before the FDA, *the issues of statutory authority and adherence to the statutory standard were faced only in this 17 October 1973 notice and only in the above quoted passages.*

In the 17 October notice the Commissioner set a deadline of 16 November 1973 for the filing of objections and requests for hearings on the provisions of the ingredient labeling regulation. Also, the Commissioner for the first time set effective dates for the regulation to be put into

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[9] 38 Fed. Reg. 28912.

[10] *Id.*

operation; the regulation was to apply to all cosmetic labeling ordered after 31 March 1974 and to all cosmetic products labeled after 31 March 1975.

Finally, in the 17 October 1973 notice, the Commissioner invited petitions for the amendment of the regulation to deal with exemptions for incidental ingredients present in cosmetic products in insignificant amounts. This action was taken in response to comments received on this issue.

In summary, the notice of 17 October 1973 sought to accomplish three goals. First, the Commissioner undertook to express his opinion on the substantive issues raised in the written comments that had been received. Second, the Commissioner added a fifth subsection to his original proposal which invited petitions from interested parties to establish specific uniform names for cosmetic ingredients. In announcing this fifth subsection, the Commissioner stated that each such petition would be subject to notice and comment procedures prescribed in the FDA regulations. Third, the Commissioner *for the first time* invited formal objections and requests for hearing to the regulation as it then stood.

This point bears repeating: it was at this stage (17 October 1973) that interested parties were first given the opportunity to exercise the procedural rights to object specified in section 701(e) of the Food and Drug Act. The point to be made is that *the form and content of the regulation were still very much open to discussion and debate as of 17 October 1973*; the Commissioner on this date envisioned that the process of informal rulemaking would proceed at least until all objections had been dealt with.[11] The majority opinion is thus *totally in error on*

[11] The statutorily prescribed manner is set forth in section 701(e) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 371(e), and is discussed in the text at notes 48 to 49, *infra*.

the critical point in its own rationale when it states: "[T]he original regulation . . . was published *in final form* in the Federal Register on October 17, 1973 (38 Fed. Reg. 28912) . . . and ICMAD's petition for review in 1975 clearly falls outside the 90-day boundary."[12] The Commissioner himself prescribed a thirty day limit on the filing of objections and requests for hearings in his continuation of informal rulemaking. (38 Fed. Reg. 28912) *There was no administration action at this date from which anyone could have sought judicial review within 90 days, and no one did.*

3. *25 July 1974.* The Commissioner reported on this date that thirteen objections and four requests for hearing had been received as the result of his notice of 17 October 1973. In response to these filings, the Commissioner prepared what he termed a "Tentative Revised Final Order." The Commissioner stated his belief that this tentative revised order adequately dealt with the objections and eliminated the need for a public hearing.

The Tentative Revised Final Order *was not published in the Federal Register* and, therefore, *one who depended on public notices as required by the Food and Drug Act would be unable to gauge the magnitude of the changes which the Commissioner made in response to the objections.* Rather, the order was sent to all parties who had filed objections and was placed on display with the Hearing Clerk of the FDA for a period of thirty days. The Commissioner also announced that he would meet privately with any parties during the period from 25 July 1974 to 23 August 1974 to discuss the proposed ingredient labeling regulation.

The informal rule making, albeit with some unusual variations, was thus continuing; there was still no final

[12] Maj. Op. 9-11 (emphasis added).

administrative action from which an appeal could be taken, and none was.

4. *3 March 1975. This is the key date* with respect to understanding the procedural history of the cosmetic ingredient labeling regulation. On this date the Commissioner divided his comunications on the subject of cosmetic ingredient labeling into two notices.

Although the Commissioner termed the communications as two separate notices, they dealt with the same subject matter, were filed with the Registrar of federal documents at exactly the same time, and were separated in the Federal Register by only a short black horizontal line. As will be seen, there is no doubt the Commissioner *wanted* the notices thought of as being separate; the question of whether this technique exalts form over substance in an unacceptable manner will be discussed at a later point.

In the first notice the Commissioner explained his reason for not holding public hearings in response to the filed objections:

> The Commissioner believes that the factual circumstances involved are well known to the *Food and Drug Administration* and that a hearing could not provide additional information.[13]

The Commissioner asserted that the private discussions he had been holding pursuant to his 25 July 1974 notice were justified by this assumed inability of a public hearing to provide additional information.

The primary purpose of this first notice of 3 March 1975 was *to promulgate significant additions to the ingredient labeling regulation which had been the focus of attention since 7 February 1973.* In this notice *the Commissioner proposed the addition of twelve subsections to the five subsections which had already been proposed.*

[13] 40 Fed. Reg. 8918 (emphasis added).

According to the Commissioner, these proposed additions contained "refinements of and alternatives to the original regulations for ingredient labeling . . . [T]he new provisions offer *alternative methods* for ingredient declaration." [14]

The Commissioner began the first 3 March 1975 notice by referring to the 17 October 1973 notice as "the first final order" for cosmetic labeling.[15] This terminology at first appears puzzling to one who reads this 3 March notice; the significance of this statement becomes apparent only when the overall purpose of the Commissioner's 3 March notices is considered. The Commissioner's intention is to have the 12 new subsections considered as a separate unit, apart from the original five subsections discussed in all previous public notices. Even though the Commissioner has stated that the proposed additions represent "refinements of and alternatives to *the original regulations,*" as of 3 March 1975 he began to consider the two sets of subsections (a-e, f-q) as separate entities. The majority opinion accepts without question this *post hoc description,* ignoring the call in the 17 October 1973 order for further informal rulemaking, ignoring the Commissioner's own actions over the intervening 17 months, and never deigning to explain *from What* the petitioner could have sought relief after the 17 October 1973 order which plainly contemplated further administrative proceedings on the proposed regulations. *The validity of the Commissioner's characterization is central to the question of the timeliness of ICMAD's petition in this court.*

As a conclusion to the first notice of 3 March 1975, the Commissioner set a deadline of 2 April 1975 for the filing of objections to the twelve proposed subsections.

[14] 40 Fed. Reg. 8919 (emphasis added).

[15] 40 Fed. Reg. 8918.

The Commissioner also set new effective dates of 3 March 1976 for ordering labels and 3 September 1976 for labeling of products. The new effective dates were to apply to the *entire regulation* (the original five plus the twelve new subsections); no attempt was made to separate the regulations for this purpose.

In the second notice published on 3 March 1975, the Commissioner dealt with the objections filed in response to the first five subsections discussed in the 17 October 1973 notice.[16] The Commissioner found substance in only two of the objections and ordered that these provisions be stayed pending a public hearing. With respect to the effect of the stayed provisions on the original 17 October 1973 provisions, the Commissioner stated that "the unstayed portions of the October 1973 order are distinct and unaffected. The Commissioner concludes that these separable parts of the October 1973 order should be placed into effect without further delay."[17]

Thus, as a result of the two notices published on 3 March 1975, the Commissioner had divided the cosmetic ingredient labeling regulation into *three* separate entities: 1) the unstayed portions of the 17 October 1973 notice (three subsections); 2) the stayed portions of the 17 October 1973 notice (two subsections); and 3) the twelve new subsections promulgated first in the notice of 3 March 1975. The logic and appropriateness of this division will be examined in a later section.

5. *30 May 1975.* In this notice the Commission dealt with the objections (which included the first written objections interposed by ICMAD) filed pursuant to the notices issued 3 March 1975. As to those objections which concerned the first five subsections originally published on 17 October 1973, the Commissioner stated that

[16] 40 Fed. Reg. 8924-26.

[17] 40 Fed. Reg. 8925-26.

> nothing in the regulations published March 3, 1975, requires the declaration of ingredients on cosmetic products. That requirement was issued under § 701.3 (a) in the order published in the Federal Register of October 17, 1973, at which time a period of 30 days was provided for the filing of objections and requests for hearing. Consequently, the objections to provisions of § 701.3(a) received in response to the announcement of March 3, 1975, are untimely, and the requests for hearing on those provisions are denied.[18]

With respect to ICMAD's objection that there was no substantial evidence to support the conclusion that the regulation was "necessary" in the statutory sense, the Commissioner stated,

> The Commissioner notes that the question whether a particular regulation prevents consumer deception or facilitates value comparisons *is a question of fact*, not a question of law. . . . Had objections and a request for hearing been made [pursuant to the 17 October 1973 notice], the Commissioner would have placed *any appropriate additional evidence* in the record at such a hearing, demonstrating that ingredient declaration prevents consumer deception and facilitates value comparisons.[19]

After dealing with the objections to the first five subsections by declaring them untimely, the Commissioner in his 30 May 1975 notice turned to the objections to the additional twelve subsections which had been promulgated on 3 March 1975. The Commissioner dealt with these objections by terming them "petitions for amendment" of the labeling regulation; that is, he denied that they were objections at all. As the Commissioner stated, "each is in fact a request that additional exemptions be granted

[18] 40 Fed. Reg. 23459.

[19] 40 Fed. Reg. 23459.

or alternative methods of labeling be permitted." [20] After labeling these objections as "petitions", the Commissioner proceeded to declare that the petitions were defective *qua* petitions in that they did not meet the statutory standards for petitions.

Thus, the objections to the twelve additional subsections were first characterized as being in a different form than the parties intended, and then were denied as not fitting into that newly designated category. *This action with respect to objections to the twelve additional subsections was taken eighty-eight days after the subsections were promulgated on 3 March 1975.*

The Commissioner did find that one objection interposed by ICMAD had merit and ordered that the provision in question be stayed pending the outcome of a public hearing. In addition, the partial stay issued 3 March 1975 was revoked. The Commissioner at this time set a new and final effective date for the labeling regulation; all labeling for cosmetic products ordered after 31 May 1976 and all cosmetic product packages labeled after 30 November 1976 were to comply with all of the requirements of the regulation except the one provision stayed in the 30 May 1975 notice. *Again, the effective dates applied to all seventeen subsections and did not distinguish between what the Commissioner termed the two separate regulations.* The notice of 30 May 1975 was the final pronouncement by FDA on this matter. There has been no citation by the parties as to the outcome of any proceedings concerning the one provision which was stayed on 30 May 1975.

II. ICMAD's Objections

ICMAD first interposed written objections on 1 April 1975; these objections were filed within the prescribed 30 days in response to the Commissioner's notice of 3

[20] 40 Fed. Reg. 23459-60.

March 1975. ICMAD objected "totally to the concept of ingredient labeling on cosmetics" in its letter to the Commissioner on 1 April 1975.[21] This objection was based on the adverse consequences of the regulation which would fall particularly hard on the type of manufacturers and distributors represented by ICMAD. ICMAD chose to mount its frontal challenge to the regulation at this point because, in its view, the twelve new subsections proposed on 3 March 1975 "in fact give no relief from the adverse effects of" the first five subsections promulgated on 17 October 1973.[22]

ICMAD also contended in its 1 April 1975 submission that the Commissioner had not made the statutorily required finding of necessity in promulgating the regulation; as ICMAD stated, the conclusion "that cosmetic ingredient labeling is necessary to prevent deception and facilitate value comparison . . . is not supported by facts, but by surmises." [23] ICMAD thus challenged the legal basis on which the regulation was promulgated.

After outlining the adverse consequences of the regulation for its membership and challenging the legal basis for the regulation, ICMAD put forth *particularized objections* to the twelve additional subsections proposed on 3 March 1975. In each case ICMAD identified what it considered the particular defect in the proposed provisions *and* offered a precise formulation of the issue on which a public hearing was requested. It is the thoroughness and completeness of ICMAD's objections which apparently inspired the Commissioner to label the objections as "petitions for amendment" and label them as defective as "petitions"; presumably if ICMAD's objections had been

[21] Letter of 1 April 1975 from ICMAD to Commissioner of FDA, J.A. at 17.

[22] *Id.*

[23] *Id.*

more cursory and far less specific they would have passed muster as objections. As stated previously, all but one of the objections were denied by the Commissioner; ICMAD's next formulation of its objections to the labeling regulation is to be found in its complaint for declaratory and injunctive relief filed on 27 August 1975.

As framed in the complaint and the petition for review, ICMAD objects to the labeling regulation on three basic grounds. First, ICMAD contends that the Commissioner acted in excess of his statutory authority by 1) treating all cosmetic products as a single commodity; 2) by failing to make a determination on a commodity-by-commodity basis that this ingredient labeling regulation is necessary to achieve the statutory objective; and 3) by requiring manufacturers to divulge all ingredients, and therefore to divulge trade secrets.

As the second ground for challenge, ICMAD argues that, even if the FPLA empowers the Commissioner to promulgate a labeling regulation governing all cosmetic products as one commodity, the Commissioner has failed to meet the statutory burdens of finding that this regulation is necessary to prevent the deception of consumers or to facilitate value comparisons.

As the third ground for challenging the regulation, ICMAD points to numerous alleged procedural irregularities which it believes render the regulation unlawful.

III. Judicial Review of Labeling Regulations

Judicial review of the cosmetic ingredient labeling regulation at issue in these cases is governed by section 701(f) of the Food, Drug, and Cosmetic Act. In relevant part this section provides:[24]

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[24] 21 U.S.C. § 371(f) (emphasis added).

"(f)(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time *prior to the ninetieth day* after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. . . . The Secretary thereupon shall file in the court the *record of the proceedings* on which the Secretary based his order, as provided in section 2112 of Title 28.

"(2) If the petitioner applies to the court for leave to adduce additional information, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (*and evidence in rebuttal thereof*) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may *modify his findings as to the facts*, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

"(3) . . . .

• • • •

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

The FDA contends that section 701(f)(1) makes review in the court of appeals the exclusive avenue for relief for ICMAD in this case. ICMAD, on the other hand, points to the "saving clause" in clause 6 to justify

district court jurisdiction in the matter. ICMAD's principal argument is that it is unsure of which court to go to in order to secure judicial review; ICMAD did, therefore, file for judicial review in the district court and in the court of appeals on the same day.

The question which will occupy the greater part of the remainder of this dissent involves the interrelationship between the saving clause and the statutorily prescribed review procedure. In particular, the issue boils down to the following question: under what circumstances is it mandatory that review of a regulation promulgated pursuant to section 701(e) be sought in the court of appeals?

IV. Analytical Framework

Congress undoubtedly has the power to designate the forum in which challenges to federal administrative action are to be brought.[25] In this regard the Supreme Court has admonished that special review procedures, such as that found in section 701(f) of the Food and Drug Act, are to be "construed both with precision and with fidelity to the terms by which Congress has expressed its wishes."[26] There are two sources which will be examined in an attempt to discern the Congressional intent as regards the proper forum in these cases brought by ICMAD. First, the words of the statute itself will be examined; this exercise will be followed by a close examination of the legislative history. After discussing the legislative intent, relevant judicial precedents, including in particular the Supreme Court's decision in *Abbott Laboratories* v. *Gardner*,[27] will be examined. In examining these various sources, the purpose is to formulate a

[25] *See, e.g., Yakus* v. *United States*, 321 U.S. 414 (1944).

[26] *Cheng Fan Kwok* v. *Immigration and Naturalization Serv.*, 392 U.S. 206, 212 (1968).

[27] 387 U.S. 136 (1967).

set of precise, relevant questions to apply to the facts of this case in order to determine the proper forum.

A. *Statutory Language.*

A literal reading of the first three clauses of section 701(f) would appear to indicate that the challenges to be heard by the court of appeals are those that are based on the *factual* findings made by the Commissioner when promulgating regulations. This conclusion derives from two statutory references. First, upon receipt of a copy of the petition for review, the Secretary is required to file with the court "the *record* of the proceedings on which the Secretary based his order. . . ."[28] *Furthermore, the statute envisions a record which can be reviewed under the "substantial evidence" test.*[29] Thus, the primary concern of the special review procedure appears to be with the factual findings made when regulations are issued.

The idea that the statutorily provided review procedure is primarily concerned with the review of factual matters finds further support in clause (2) of section 701(f). This section provides that a petitioner may request that the court of appeals order the taking of additional evidence before the agency. Significantly, such additional evidence must also include *rebuttal evidence.* After taking the additional evidence, the statute authorizes the Secretary at his discretion to "*modify* his findings as to the facts, or make *new* findings by reason of the additional evidence. . . ."[30] In so stating, the implication is clear that the Secretary has *already* made factual findings based on the record sent to the court of appeals. Clause (2) merely provides for the addition of evidence

[28] 21 U.S.C. § 371(f)(1) (emphasis added).

[29] *Id.* § 371(f)(3).

[30] *Id.* § 371(f)(2) (emphasis added).

to that original record. Clause (2) also requires the Secretary to file his new or modified findings with the court; such a requirement serves to ensure that the court of appeals has the fullest possible record on which to review the factual findings of the Secretary.

In summary, a reading of *the statutory language yields the conclusion that review in the court of appeals is premised on the existence of two conditions:* 1) *a record* which is 2) capable of being reviewed for *substantial evidence. If there is no record, or if it is such that cannot be meaningfully reviewed for substantial evidence, the implication is that the saving clause in § 701(f)(6) provides the remedy.* This implication flows from the positioning of the saving clause at the end of the subsection which specifies the statutory review procedure; if the special procedure is not applicable, then the saving clause must come into operation. The fuller meaning and intent behind the special review procedure and the saving clause will now be explored by examining the legislative history.

B. *Legislative History.*

As stated previously, the legislative history is of great importance in these cases.[31] While recognizing the importance of this source of information, it is appropriate to qualify this characterization with two observations.

First, the Food and Drug Act was enacted in 1938, over a decade before the Administrative Procedure Act went into effect. The Food and Drug Act, in its judicial review provisions, uses such terms as "order," "substantial evidence," and "record." These terms were later incorporated into the APA and given somewhat more precise definitions than existed in the pre-APA period.[32]

[31] *See* text and note at note 26, *supra.*

[32] 5 U.S.C. § 551 *et seq.*

In addition, these terms have undergone some significant redefinition in recent years as the courts have begun to focus more heavily on the review of federal agency action. Therefore, it would serve no useful purpose to search the legislative history of the Food and Drug Act to determine the precise intent with respect to some of these key terms which have gone through at least two stages of redefinition. Rather, in a case such as this, the legislative history should be consulted in order to identify the basic underlying congressional concerns. Once these underlying concerns have been identified, a court can then seek to reconcile these concerns with the current, accepted tenets of federal administrative law. Such an approach in no way denigrates the importance or significance of congressional intent but merely recognizes that the intent expressed in 1938 cannot control current court actions with total specificity.

Second, the fact that the FPLA incorporates by reference the judicial review provisions of the Food and Drug Act is of some significance in this case. At the time it was enacted, the Food and Drug Act represented a marked increase in federal interest and activity in protecting consumers in an area in which they are particularly vulnerable—food and drugs. The legislative history is filled with frightening stories concerning the effects of unsafe, untested, and adulterated food and drug products which made their way on to the market because of the lack of effective regulation. The point to be made is that the subject matter of that legislation was a very important factor in the fashioning of the judicial review provisions. The FPLA deals with a different subject matter of somewhat diminished potential impact on the public; it is not that the FPLA is any less important a piece of legislation, but the concerns underlying the two laws are different. This point should be kept in mind as the analysis proceeds.

There is a preliminary matter which deserves mention before proceeding to the primary areas of inquiry. Section 701(f) refers to the review of "orders" in the court of appeals. Such terminology in other statutory schemes has, in the past, caused courts of appeals to refuse to review "regulations" on the grounds that they are not "orders" as specified in the statutory review provisions. Many,[33] but not all,[34] appellate courts have found ways to circumvent this narrow view of "order" so as to review regulations which are the product of informal, notice-and-comment rulemaking. At first glance, this issue would appear to be present in the cases brought by ICMAD; on closer examination, however, the legislative history resolves the issue in favor of the review of "regulations" as well as "orders." Throughout the legislative history reference is made to orders *and* regulations;[35] the statutory language itself, however, makes reference only to orders. Thus it appears clear that Congress intended to encompass regulations within the special review provision.

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[33] *See, e.g., Investment Co. Inst.* v. *Board of Governors of the Federal Reserve Sys.*, 551 F.2d 1270 (D.C. Cir. 1977); *Deutsche Lufthansa Aktiengesellschaft* v. *CAB*, 479 F.2d 912 (D.C. Cir. 1973). *See also* Verkuil, *Judicial Review of Informal Rulemaking*, 60 Va. L. Rev. 185, 196-205 (1974).

[34] *See, e.g., PBW Stock Exch.* v. *SEC*, 485 F.2d 718 (3d Cir. 1973), *cert. denied*, 415 U.S. 951 (1974).

[35] *See* C. Dunn, *Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record* (1938) at 824 (House Report No. 2139, 75th Cong., 3d Sess. (1938)); at 995 (Conference Report, House Rep. No. 2716, 75th Cong., 3d Sess. (1938)) (hereinafter referred to as Dunn). The Dunn work is a compilation of the Reports and Debates on the Act. Page citations will be to the Dunn work with a notation in parenthesis as to Report or Debate which is the source of the citation.

There are two primary questions concerning the statutorily prescribed review provision which must be posed and answered. First, why have a special review procedure at all? Second, why designate the court of appeals as the forum in which to bring the challenges encompassed by the special review procedures. These questions will now be examined in turn.

1. *Why have a special review procedure?* In considering the question of judicial review in the various deliberations concerning the Food and Drug Act, the suggestion was seriously put forth on numerous occassions that the regulations of the FDA be made unreviewable in the courts.[36] These suggestions of non-reviewability did not prevail; indeed, the Conference Report on the legislation indicates that the "type of judicial review provided . . . is as broad as the Constitution permits in the case of review by a constitutional court."[37] Once this commitment to the concept of pre-enforcement judicial review of FDA regulations had been made, it remained to work out the details of the review procedures.

During the legislative consideration of the Food and Drug Act, it became clear that the legislators believed that the basic validity of regulations could be tested in the courts through the injunctive and declaratory judgment remedies *without* any express provision for such review in the statute.[38] The legislators did not, however, believe that factual determinations were reviewable in equity in

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[36] *See, e.g.*, Dunn, *supra* note 35, at 834-39 (H.R. Rep. No. 2139, Part 2, Minority Views, 75th Cong., 3d Sess., 1938)); 873-85 (Debate in the House, June 1, 1938).

[37] *See* Dunn, *supra* note 35, at 995 (Conference Report, House Rep. No. 2716, 75th Cong., 3d Sess. (1938)).

[38] *See, e.g.*, Dunn, *supra* note 35, at 938 (Debate in the House, June 1, 1938) (remarks of Congressman Mapes). *See also*, 83 Cong. Rec. 7892 (1938).

the absence of a special statutory review procedure.[39] Congress believed that it was important to be able to test these many underlying technical factual determinations during the pre-enforcement period; thus, the basic decision was made to include a specific pre-enforcement review procedure to ensure that the commitment to the concept of full judicial review would be carried out. The concern for the factual predicate of FDA regulations lay at the core of the decision to adopt a special review procedure.

2. *Why designate the court of appeals?* The reasoning behind this designation of the appellate court is important for purposes of this analysis. Throughout the lengthy[40] legislative consideration of the Food and Drug Act, the district court had been specified as the proper forum in which to challenge FDA action;[41] the language used in these preliminary drafts was nearly identical to the language eventually adopted, with the exception of the reference to the court of appeals in the final version. It was not until the conference between the House and the Senate, which was convened to resolve the differences between the respective versions of the legislation, that the court of appeals was substituted for the district court as the statutory review forum.

The court of appeals was substituted for the district court because judicial challenges "would be confined to 10

[39] See 83 Cong. Rec. 7772-7773, 7781-7784, 7893-7899 (1938); *see also Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 143 (1967).

[40] The original bill leading to the enactment of the Food, Drug and Cosmetic Act of 1938 was introduced in June, 1933. *See* S. 1944, 73d Cong., 1st Sess. (1933). Legislative activity in this area of food and drug regulation was extensive during the period from 1933-38; *see generally*, Dunn, *supra* note 35.

[41] *See* Dunn, *supra* note 35, at 810-811, 825 (H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938)).

circuits instead of to 85 districts." [42] The very considerable controversy surrounding judicial review had centered on the fact that any district judge could delay the implementation of important regulations designed to protect the health and safety of the public. As one participant in the congressional debates stated,

> With 85 different district courts, just think of the chance a chain store has. It could undoubtedly prolong litigation and hold it up in one State after another.[43]

With the court of appeals as the statutory forum, the number of potential forums for challenges would be reduced and the possibility of endless, harassing litigation would also be reduced.

Thus the choice of forums in the Food and Drug Act emanated from considerations apart from those dealing with a division of functions between the district and appellate courts. That is, *Congress did not reason that, since appellate courts regularly perform a reviewing function they should be assigned the reviewing function in the case of FDA regulations.* Rather, the reasoning rested on the desire to channel any challenges to FDA orders into the level of the federal judicial system which has fewer forums.

What is the import of this congressional intent for the cases brought by ICMAD? The primary message is that any decision to designate the district court as a proper forum in these cases must take into account the congressional concern about the delay in implementing regulations, keeping in mind that the subject matter of the regulations in these cases is different from the subject matter which

[42] *See* Dunn, *supra* note 35, at 938 (Debate in the House, June 1, 1938) (remarks of Congressman Mapes).

[43] *See* Dunn, *supra* note 35, at 940 (debate in the House, June 1, 1938) (remarks of Congressman Sauthoff).

was the focus of congressional discussions surrounding the enactment of section 701(f).[44] If proper and careful notice is taken of this concern about the proliferation of challenges and possible delay, the congressional purpose in designating the court of appeals as opposed to the district courts will be vindicated.

There is another relevant message to be taken from the legislative history. *As noted, the Congress did not consider the comparative qualifications of the district and appellate courts when designating the latter as the statutory forum.* Congress has not, therefore, pre-empted a consideration of these factors. *It is appropriate for a court to consider these factors when making a determination relating to forum;* and this determination can be made in this context without deviating from congressional mandate since these factors did not significantly influence the legislative decision.

3. *The saving clause.* There remains the question of the purpose and significance of the saving clause found in section 701 (f) (6). There is no question that this clause applies to regulations promulgated under section 701(e), as was the regulation at issue in these cases brought by ICMAD. Discerning the congressional intent concerning the clause is somewhat more difficult.

The House version of the Food and Drug Act was the source of the saving clause. The Senate conferees specifically adopted this House version; the House Report indicates that:

> There is also saved as a method to review a regulation . . . whatever rights exist to initiate a historical proceeding in equity to *enjoin* the enforcement of the regulation, and whatever rights exist to initiate a *declaratory judgment* proceeding.[45]

[44] *See* discussion at 25 to 26, *supra.*

[45] *See* Dunn, *supra* note 35, at 825 (emphasis added) (H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938)).

The clear implication of this evidence, and the evidence surrounding the decision to adopt a special review procedure,[46] *is that a complaint for declaratory and injunctive relief on the grounds that the Commissioner's action are ultra vires is not subject to the special review procedure of section 701(f).* Such an action would, however, be appropriate in a district court. It therefore can be concluded that review in the court of appeals was *not* meant to be exclusive; the question of when such review would be appropriate under this statutory scheme will now be faced.

4. *The "record" and "substantial evidence."* As noted previously, these terms have undergone significant redefinition since the Food and Drug Act was enacted in 1938.[47] Nevertheless, the legislative history does yield significant information concerning these terms which must be taken into account in making the decision regarding the proper forum.

Section 701(e) defines the procedures to be followed in promulgating regulations such as the one at issue in these cases. This section prescribes a multi-phase rulemaking procedure which combines most of the attributes of *both* informal and formal rulemaking. In effect, the first phase of these proceedings is similar to a section 553 notice-and-comment proceeding as prescribed in the APA: the publication of a notice of proposed rulemaking, the solicitation of comment, and the publication of an order setting forth the rule.[48] It is at the end of this proposal-comment-order stage that the section 701(e) procedure becomes quite complicated; at this point, any person who will be adversely affected by the proposed rule has the right to object and to request a formal hearing.[49]

[46] *See* text at notes 36 to 39, *supra.*

[47] *See* text at notes 32 to 33, *supra.*

[48] 5 U.S.C. § 553.

[49] 21 U.S.C. § 371(e)(2).

The legislative history clearly indicates that a full-fledged, trial-type hearing was intended,[50] and the FDA regulations carry out this intention.[51] The formal hearing is conducted by an APA hearing examiner;[52] the hearing "is directed to receiving factual evidence and expert opinion testimony related to the issues in the proceeding."[53] Witnesses are sworn and are available for cross-examination by any participant.[54] Objections to the admission or rejection of evidence, or to limitations of the scope of examination are entertained.[55] A stenographic record of the hearing is made, and the record may be corrected at the conclusion of the hearing.[56] The transcript, exhibits and any written argument that may have been filed at or in connection with the hearing constitute "the exclusive record for decision."[57]

The final order which evolves from these two stages in the section 701(e) rulemaking process must "be based only on substantial evidence of record" at the hearing.[58] If the two stages have been employed, the final order contains

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[50] *See* Dunn, *supra* note 35, at 824 (H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938)). ("While common law or jury trial rules of evidence need not be enforced at such a hearing, nevertheless it is *essential* that all the evidence on which the administrative officer acts be disclosed at the hearing and that the *right to contravert viva voce* be accorded.") (emphasis added).

[51] 21 C.F.R. § 2.48 *et seq.*

[52] *Id.* § 2.71.

[53] *Id.* § 2.79.

[54] *Id.* § 2.81.

[55] *Id.* § 2.83.

[56] *Id.* §§ 2.90(a), 2.93.

[57] *Id.* § 2.94.

[58] 21 U.S.C. § 371(e)(3).

detailed findings of fact and conclusions by the Commissioner. This entire record is the record which is filed with the court of appeals pursuant to the special statutory review procedure found in section 701(f)(1).

The FDA conducts the overwhelming vast majority of its rulemaking proceedings under section 701(e) without going beyond the proposal-comment-order stage.[59] How is this done? It has been accomplished by introducing an element of discretion into the Commissioner's determination as to when a hearing is warranted by an objection; a hearing will be granted only when the Commissioner concludes that there is a "reasonable ground" therefor.[60] The Commissioner has developed an extremely strict notion of the type of objections which are sufficient to trigger a formal hearing. Moreover, the Commissioner has also developed a "summary judgment" type procedure, as used in these cases, to deny the reasonableness of objections.[61] The Commissioner will evidently go to great lengths to avoid the burdens imposed by a formal hearing.

The parameters of the Commissioner's authority to deny objections in a summary manner has not been settled; this is not the place in which to address the merits of that controversy.[62] *But the summary procedure does*

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[59] *See* Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 Cal. L. Rev. 1276, 1283-84, 1287 (1972).

[60] 21 C.F.R. §§ 2.48, 2.67(b)(5).

[61] *See* 21 C.F.R. § 2.67(c); *see also*, Hamilton, *supra* note 59, at 1287 n.69; Verkuil, *supra* note 33, at 192.

[62] The Supreme Court has approved FDA's use of a summary judgment procedure for the denial of requests for a hearing pursuant to the withdrawal of a new drug application under section 505 of the Act, 21 U.S.C. § 355. *See Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609,

have significant implications for the issue of the proper forum in which to challenge FDA regulations. The point to be drawn from the discussion is that the statute envisions a rather complete record being developed when there is substantial controversy surrounding one or more provisions of a proposed regulation. That is, the Congressional intent was that objections would lead to a *structured dialogue* between the affected party and the agency *and such dialogue would take place within the framework of a formal hearing. No such formal hearing took place in response to objections by ICMAD or any other affected party.* According to the statute, judicial review of a regulation is to take place on the basis of the record as developed in the two stages of the proceeding outlined above.

It is clear from the legislative schemata and debate that the type of record developed in the ICMAD case here was envisioned as an appropriate record only when the factual bases on which the Commissioner proceeded went unchallenged. Such is not the case with ICMAD.[63] The failure to hold a hearing thus embodies a different message in the context of FDA regulations; such a failure does not mean that there are not numerous controversies as to the facts, but that the controversies have not met the extremely high standard set by the Commissioner in his efforts to avoid a formal hearing. When compared with the legislative intent as to what the record before the court of appeals *should be*, the record as compiled before the Commissioner is artificially limited because of his

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620-622 (1973). The withdrawal of a new drug application does, of course, present a situation somewhat different from the ICMAD cases involving the promulgation of cosmetic labeling regulations through rulemaking.

[63] ICMAD has indeed challenged the factual bases on which the Commissioner proceeded. *See* text at page 16 and notes 21 to 23, *supra.*

concern over the burdensomeness of the formal hearing process, to put the extraordinary procedure employed by the Commissioner in the most charitable light.

It is possible to discern from the legislative history some concept of what was meant by "substantial evidence." The legislators conceived of this term as having a qualitative as well as a quantitative dimension. That is, it was intended that the evidence relied upon by the Commissioner in promulgating regulations would be tested by opposing evidence.[64] The technique of the public hearing was to suffice to inject this element of adversariness into the procedures prescribed in section 701(e). *This concern for the introduction of adverse evidence is a definite theme in the legislative history. There was no such testing of the evidence in this case.*

C. *Abbott Laboratories* v. *Gardner*

The Supreme Court has rendered an interpretation of some aspects of section 701(f) in *Abbott Laboratories* v. *Gardner*[65] and two companion cases,[66] and both parties to the cases here have placed great emphasis on the rationale of these Supreme Court cases. In *Abbott* a group of drug manufacturers brought suit in the district court seeking declaratory and injunctive relief with respect to a labeling regulation promulgated by the Commissioner. The district court granted the relief but the Third Circuit reversed on the grounds that the district court lacked subject matter jurisdiction. The Supreme Court granted certiorari and reversed, thus upholding the exercise of district court jurisdiction.

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[64] *See* note 50 *supra.*

[65] 387 U.S. 136 (1967).

[66] *Toilet Goods Ass'n, Inc.* v. *Gardner*, 387 U.S. 158 (1967); *Gardner* v. *Toilet Goods Ass'n, Inc.*, 387 U.S. 167 (1967).

The regulations in *Abbott* and the companion cases were promulgated under section 701(a) of the Food and Drug Act; the regulation in these cases brought by ICMAD was promulgated pursuant to section 701(e). The difference in the source of the statutory authority is quite significant as regards the relevance of the *Abbott* case to the cases brought by ICMAD. There is no special statutory review procedure (*i.e.*, court of appeals review) applicable to regulations promulgated pursuant to § 701(a). Thus, in *Abbott* and the companion cases the question of the proper forum was not raised by the parties or addressed by the Supreme Court; indeed, the Court specifically avoided this issue.[67] Rather, the issue presented was whether the special statutory review procedure applicable to § 701(e) regulations meant that § 701(a) regulations were immune from *pre-enforcement* judicial review. The *Abbott* case thus resolved around the issue of allowable remedies, not the issue of the proper forum.

In holding that pre-enforcement judicial review of § 701(a) regulations was proper, the Court discussed the saving clause found in § 701(f)(6). The Court first drew the important conclusion that the saving clause applied to § 701(a), not just to section 701(e) as the government had contended[68] and as Justice Fortas argued in dissent.[69] *The Court went on to conclude from the legislative history that the remedies of injunction and declaratory judgment were encompassed within the intended meaning of the saving clause.*[70] Since the saving clause applied to § 701(a) regulations, it was appropriate for the plaintiff in *Abbott* to seek these remedies. For pur-

[67] *Toilet Goods Ass'n, Inc.* v. *Gardner*, 387 U.S. 158, 165 n.3 (1967).

[68] 387 U.S. at 144-46.

[69] 387 U.S. at 180.

[70] *Id.* at 144-146.

poses of these cases brought by ICMAD, this conclusion is quite important in that *it confirms the notion that Congress intended through § 701(f)(6) to save the very remedies which ICMAD sought in the District Court.* The Court in *Abbott* did not specify the forum in which challenges to FDA regulations could be made, but it did make a significant statement concerning the nature of the remedies preserved to the parties.

In discussing the saving clause, the Court in *Abbott* stated that "when the special provisions [§ 701(f)] apply, presumably they must be used . . . ."[71] In so stating, the Court expressed the generally accepted conclusion that judicial review is generally to occur in the forum and in the form specified in the statute. But this statement, as true as it is, does very little to aid in the disposition of the cases brought by ICMAD, since the statement merely expresses a conclusion. The statement does not attempt to delineate the conditions under which the special provisions *do apply* and must therefore be employed. There are, however, two relevant pieces of evidence in the *Abbott* case as to when the remedies preserved in the saving clause (*i.e.*, injunction and declaratory judgment) might be employed.

First, the Government in *Abbott* argued that the saving clause is applicable to regulations promulgated pursuant to section 701(e) when such regulations are issued "without affording the required public notice and opportunity to file objections and to request a public hearing."[72] Under these circumstances, the Government contended that "an equity proceeding or a declaratory judgment action . . . might be entertained on the ground that the statutory procedures had not been followed."[73]

[71] *Id.* at 146.

[72] *Id.* at 146 n.14.

[73] *Id.*

Such an argument is certainly possible in these cases brought by ICMAD.[74]

Second, in dissent Justice Fortas argued (unlike the majority) that the saving clause applied only to section 701(e) regulations. In a footnote, he further argued that the saving clause

> was intended to save the remedies of injunction and declaratory judgment where the agency promulgated a subsection (e) regulation *without the hearings and findings needed to permit review in the Court of Appeals.*[75]

Although the legislative history nowhere contains such an explicit statement of the purpose of the saving clause, Justice Fortas' interpretation is certainly consistent with the legislative intent. That is, Congress in the Food and Drug Act made the basic policy judgment that regulations such as the one at issue in the ICMAD cases should be subject to pre-enforcement review. *Congress went further and specified that pre-enforcement review, under certain circumstances,*[76] *was to be in the court of appeals. If those circumstances were not present, the saving clause reserved review in the District Court.* This is also my view; in the preceding sections I have developed the major points mentioned above more fully. The statutory language, the legislative history, and the leading case on the issue support my view of the purpose and operation of the saving clause.

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[74] ICMAD has indeed challenged the procedures employed by the FDA in this case and, from the discussion at notes 8 to 20, *supra*, there is a colorable argument to be made in this regard.

[75] 387 U.S. 180, n.5.

[76] *See* discussion at notes 40 to 43, *supra*.

From the above, it is apparent that the majority's reliance on *Nader* v. *Volpe*[77] is misplaced. *In the middle of a rulemaking proceeding* before the National Highway Traffic Safety Administration, plaintiff brought suit in *Nader* seeking to compel the inclusion of certain documents in the hearing record. The District Court denied relief and on appeal this court found the District Court to be without jurisdiction. It did so based in part on the doctrine of exhaustion, specifically citing the need (1) to avoid premature interruption of agency proceedings (2) to permit the agency to exercise its expertise and discretion on a technical factual matter, and (3) to conserve agency and judicial energies.[78] Moreover, the court observed that once the agency action had become final, it could be adequately reviewed under the special court of appeals review procedures specified in the Act.[79]

In other words, *Nader* involved an attempt to seek review of non-final agency action in District Court under circumstances in which the special court of appeals procedures were applicable. In contrast, in the case at bar, review is being attempted of final agency action which is not amenable to the special court of appeals review procedures set forth in the statute.

The majority cites *Nader* for the proposition that "when Congress has specified a procedure for judicial review of administrative action, that procedure is the exclusive means of review unless, because of some extraordinary circumstances, the procedure fails to provide an adequate remedy."[80] However, this begs the question. The issue here is precisely whether Congress intended

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[77] 466 F.2d 261 (D.C. Cir. 1972).

[78] 466 F.2d at 265-268.

[79] 466 F.2d at 269-271.

[80] Majority Opinion at page 3.

the special review procedures to apply to the kind of agency action here challenged. As I have demonstrated from the statutory language, the legislative history, and case law, Congress did not intend to apply these review procedures to such action.[81]

D. *Relevant Precedents in this Circuit.*

The recurring problem of the choice as to a proper forum in situations analogous to these cases has been fully discussed in other opinions of this court.[82] No ironclad rule concerning this issue has, or could be, developed. The statement which is now generally accepted in this circuit and which comes the closest to establishing a general guideline in this matter comes from the court's opinion in *Deutsche Lufthansa Aktiengesellschaft* v. *CAB*:

> It is the availability of *a record for review* and not the holding of a quasi judicial hearing which is now the jurisdictional touchstone.[83]

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[81] In *Nader*, Judge Robinson noted:

> "The legislative history of the [National Traffic and Motor Vehicle Safety] Act is almost completely silent as to the exclusivity or concurrency of the review procedure which it specifies." 466 F.2d at 265-66.

Such is certainly not the case with the Food and Drug Act. Although it doubtless would be better if, as Judge Leventhal has suggested, Congress were to enact a general solution to the choice of forum problem (see *Investment Company Institute v. Board of Governors of the Federal Reserve System*, 551 F.2d 1270, 1283 (Leventhal, J., concurring)), we do not now have such a general solution, and legislative intent as expressed in individual laws must serve as the primary guidepost in this area.

[82] *See Investment Co. Inst.* v. *Board of Governors of the Federal Reserve Sys.*, 441 F.2d 1270 (1977); *Deutsche Lufthansa Aktiengesellschaft* v. *CAB*, 479 F.2d 912 (1973).

[83] *Deutsche Lufthansa Aktiengesellschaft* v. *CAB*, 479 F.2d 912, 916 (1973) (emphasis added).

This view has been widely accepted by other courts as well.[84]

The statement that a record for review is necessary for appellate court jurisdiction is not very helpful in the circumstances of ICMAD's case, for it, like the Supreme Court's statement in *Abbott*, is also merely a conclusory statement which does not attempt to define *when* a record is appropriate for judicial review. There is *a* record in this case, but is it sufficient? The statement that the existence of a record is the jurisdictional touchstone thus should be the beginning of the analysis in many cases, not the end. This failure to address the question of the sufficiency of the record pervades the case law; courts have not articulated guidelines to make the decision as to the sufficiency of the record. The first source of guidance on the type of record needed for review should, of course, be the statute and its legislative history; this examination has already taken place above.[85] Beyond that, the case law provides little help as to how to conduct this necessary inquiry. It is to this area left largely untouched in the case law that I now turn.

V. The Record in the ICMAD Case.

The record on which the review of the cosmetic ingredient labeling regulation would be based in this court consist of eight volumes of evidence. The overwhelming majority of the evidence consists of the written comments submitted by private citizens and commercial enterprises with an interest in the economic impact of the regulation. There has been *no hearing* held during the period in which the regulation was promulgated. *There are no formal findings or conclusions presented by the Com-*

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[84] *See* cases cited, *id.*

[85] *See* text as notes 31 to 64, *supra*.

missioner. The evidence is presented straightforwardly, with *no reference to what the Commissioner found to be convincing or unconvincing*. Indeed, there is no overt indication that the Commissioner actually took any of the proffered information into account when promulgating the regulation.

In sum, *the record is similar to that filed in a typical case covered by section 553 of the APA*. It appears clear that the record, as described above, is not the type of record which Congress intended for the court of appeals to review. The abbreviated form of the record is due to the Commissioner's actions in denying all requests for hearings on various provisions, even though there were unresolved questions of fact and statutory interpretation surrounding the filed objections. I shall assume, *arguendo*, that the Commissioner's denials of formal hearings can be considered legal. Given this assumption, *the relevant question becomes: is the record that has been presented a sufficient basis on which to conduct appellate review of the regulation pursuant to section 701(f)(1) of the Food and Drug Act?* This question will be answered by examining the grounds on which ICMAD has challenged the labeling regulation.

ICMAD has contended that the Commissioner's finding that the regulation is necessary is not supported by *substantial evidence*. Can we review this determination for such evidence on the basis of the informal comments and the Commissioner's conclusory statement which are the only evidence before us? I suggest that the answer to this is clearly no. As stated in this court's opinion in *Mobil Oil* v. *FPC*, "Informal comments simply cannot create a record that satisfies the substantial evidence test." [86] This view seems particularly appropriate in light

[86] *Mobil Oil* v. *FPC*, 483 F.2d 1238, 1260 (1973).

of the legislative history on the meaning of substantial evidence in this context.[87]

The Commissioner has admitted that the finding as to necessity is a factual matter.[88] Even more significantly, the Commissioner has admitted that *he has evidence* to support a factual finding of necessity but *he refuses to put it in the record* because of his view that the objection was not timely filed. There was a similar objection filed earlier in the proceedings which prompted the Commissioner's defense of his finding of necessity on 17 October 1973, and the Commissioner failed to insert evidence at that time. The point is that this court is denied this vitally important information which is *admittedly* in the possession of the promulgating authority. *The court of appeals is asked to make substantial evidence determination on the basis of untested, unorganized, random, informal comments at the same time that the Commissioner claims to have the type of evidence that the statute envisions to support his finding.*

A court simply must look into the factual predicates of the Commissioner's determination that he has met the requirements of the statutory standard.[89] This cannot be done on the basis of this record before the court of appeals. This court could not apply the substantial evidence test to this aspect of ICMAD's challenge. *The district court, on the other hand, could elicit further facts concerning this issue and therefore inject that element of adversariness envisioned in the statute and the legislative history*. Since recourse to the district court

[87] *See* notes 50, 64, *supra*.

[88] *See* note 19, *supra*.

[89] *See Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971); *see also* Currie & Goodman, *Judicial Review of Federal Administrative Action: Quest for the Optimum Forum*, 75 Colum. L.Rev. 1, 42 (1973).

is clearly an option provided in the statute, this is an appropriate situation in which to employ that mechanism. *The district court can develop the type of record on this point that the Food and Drug Act intended to be presented to the court of appeals.*

ICMAD also challenges the labeling regulation on the grounds that the Commissioner exceeded his statutory authority in several respects.[90] It has been stated that "legal" issues, or issues of statutory construction, need not first be addressed by the district court in these situations where the question of the proper forum is ambiguous.[91] But these assertions rest on an important premise that is not present in these cases; the premise is, as the court in *Deutsche Lufthansa Aktiegengesellschaft* stated, that "evidence has been assembled before the agency and *is not challenged*, and where the issues presented are legal and not factual." [92] In this case evidence was *assembled* before the agency (in an informal manner); but it is indeed challenged. No challenge by any party was given the treatment of an adversary hearing, because of the Commissioner's attempt to avoid the burden of a trial-type hearing as specified in the statute. There was no explanation for why the challenges (objections) were denied in many instances; in others, the explanation was quite terse and conclusory.

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[90] *See* text at notes 21-23, *supra*.

[91] *See, e.g., Deutsche Lufthansa Aktiengesellschaft* v. *CAB*, 479 F.2d 912, 916 (D.C. Cir. 1973).

[92] 479 F.2d at 916 (emphasis added). *See also Investment Co. Inst.* v. *Board of Governors of the Federal Reserve Sys.*, 551 F.2d 1270, 1278 (D.C. Cir. 1977), where the court states that

> "The issues of statutory construction which appellants raise, if ripe, clearly could be resolved on the basis of the administrative record."

Such is not the situation here; see text at note 93, *infra*.

If the evidence before an agency is unchallenged, a court makes the determination as to statutory authority with some confidence that the decision conforms with the realities of the larger setting in which the federal regulatory action is to take place. No such confidence could attach to a decision by this court in this case on the record before it. There is ample evidence to believe that the fact-gathering function has been artificially stifled in this case; we are left with an incomplete picture of the business practices, operating techniques, and possible ramifications for the industry which is subject to the regulation. Without some knowledge of these facts, we could not really understand what Congress was attempting to accomplish through the FPLA; without this knowledge, we could not determine if the Commissioner was operating within the scope of his authority under the statute. Some factual basis is needed even to make these decisions regarding statutory authority;[93] we have not been presented with them, and we could not develop them ourselves.

Since the option of district court review is available in this case, this would appear to be a particularly appropriate time to opt for such review. Not only could the court *find* additional facts, but it could perform the additional valuable function of organizing and ordering the factual presentation so as to facilitate review in this court. Therefore, I conclude that *the record before us is insufficient as a basis to review even the "legal" questions regarding statutory authority.*

Given the Congressional concern about the delay in implementing regulations promulgated pursuant to section 701(e), this concern must be fully dealt with. As stated previously, the concern for delay can be assigned a lesser

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[93] *See* Currie & Goodman, *supra* note 89, at 42 ("Statutory authority, although a 'legal' question, is often dependent upon the existence of certain facts.")

role in the context of the FPLA than it was in the context of the Food and Drug Act.[94] In addition, the delay resulting from district court review in these cases is not of the same variety as feared in the legislative history of the Food and Drug Act. There the fear was that there would be repeated challenges, each of a different nature, in numerous district courts around the nation. The fear was that the regulation might *never* go into effect because of the repeated instances of court challenges.

District Court review in this case will cause delay, but it would not be delay of a substantial or damaging nature. The FDA has itself delayed for long periods in finally putting the regulation into effect. During the various stages of promulgation, many objections were worked out to the apparent agreement of the private parties and the agency. ICMAD's remaining objections are limited in number and narrowly focused; there is no reason to think that litigation would proliferate in the district courts. In addition, ICMAD, as one entity, represents all those parties who continue to have objections and who wish to secure judicial review of the regulation. Thus, the fear that there are numerous parties to challenge the regulation in different forums is not present in these cases.

In addition to the fact that delay in this instance would not be substantially detrimental, the compensating advantages of district court review must be considered. District Court review will add order to the process of judicial review by providing that structured dialogue between the agency and the affected parties that is envisioned in the Food and Drug Act. Review in this court will therefore take place with a more realistic view of the various aspects of the regulation at issue and the

[94] *See* text at note 44 and p. 25 to 26, *supra*.

resulting revision is likely to be a more meaningful one which accomplishes the purposes of pre-enforcement review as enunciated in the legislative history of the Food and Drug Act. Thus, any disadvantages resulting from delay will be overcome by this more orderly, reflective, and thorough method of review.

In conclusion, my view is that review in the district court is proper in the ICMAD case. The conclusion rests on the following line of reasoning:

1) Review of section 701(e) regulations is *not exclusively vested* in the court of appeals;

2) Review in the court of appeals was intended in those instances where there is a *record* which can be reviewed for *substantial evidence*;

3) The saving clause preserves the *remedies of injunction and declaratory judgment* to the parties in those instances where the special review provisions do not apply;

4) The special review provisions do not apply in this case because of the *nature of the record and the issues presented*; and,

5) Therefore, *a suit for injunctive and declaratory relief is both proper and appropriate in this case* as an effectuation of both legislative intent and sound judicial policy in supervising an orderly, efficient, and effective system of judicial review of federal administrative action.

VI. Timeliness Argument

The benefits and virtues of withholding judicial review of administrative action until such action is "final" have been well documented.[95] Much of the writing on this

[95] *See Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 148 (1967); 3 Davis, *Administrative Law Treatise*, Ch. 21 (1958); Jaffe, *Judicial Control of Administrative Action*, Ch. 10 (1965).

subject deals with the advantages of such a policy for the effective operation of the agencies and the courts. The policy, however, is also dictated by another significant concern. *Prior to "final agency action," a party cannot be certain that it will be adversely affected or aggrieved by the agency action so as to justify and support a judicial challenge to the agency action.* This important concept of "final agency action" has been distorted by the FDA and the majority of this court in this case to the detriment of ICMAD in its efforts to secure judicial review.

The FDA's argument with respect to timeliness hinges on the propriety of the Commission's notices of 3 March 1975 in which he separated the originally proposed five subsections from the twelve subsections first promulgated in that same notice of 3 March 1975. In my view the regulation cannot be separated in such a way. *All seventeen subsections, taken as a whole, are what controls the conduct of the parties subject to the regulation. The subsections are, in other words, the regulation.* Indeed, the twelve subsections promulgated on 3 March 1975 provide, in the Commissioner's words, *alternate means* of complying with the substantive provisions of the first five subsections. In his notices of 3 March 1975 the Commissioner recognizes that a party will not know how to conduct itself so as not to violate the law until the *entire* regulation is placed into effect.

At other times however, the Commissioner insists on labeling the two sets of subsections as being independent; this insistence apparently stems from his desire to make as much of the regulation final as possible to ameliorate some of the effects of the prolonged delays that had already taken place and to insulate the basic concept from judicial review. The Commissioner accomplished this goal but did so by doing violence to the concept of finality. *It is well settled that a court will not accept the post-*

hoc rationalizations of counsel to explain the reasons for agency action;[96] *the same reasoning should apply to the Commissioner's attempt retroactively to divide that which is not logically divisible in the first place.*

At oral argument before this court the Government's counsel indicated that the first five subsections became final 30 days following their promulgation on 17 October 1973. Since dialogue with the court demonstrated that this position was not legally secure, since the FDA did not publish notice of its finality in the Federal Register, counsel also argued that 3 March 1975 was the "outside date" for the finality of these five subsections. The fatal weakness of this is that the objections filed pursuant to the 3 March 1975 notice were not answered until 30 May 1975, some eighty-eight days after the regulation became "final" in the FDA's view. *Following this view, ICMAD would have had but two days to assess the Commissioner's responses and file a petition in the court of appeals.* (This assumes, of course, that ICMAD received its copy of the Commissioner's response on the day it was dated, 30 May 1975). *Thus, merely by delaying its response to objections, FDA has created a situation in which it can in effect insulate its actions from review by delaying its summary denial of objections.* The record of these proceedings is replete with such examples of the "no-win" posture in which ICMAD has been placed by the combination of events that have taken place. I point to this one as merely being illustrative of the difficulties faced by ICMAD in dealing with the FDA's concept of administrative procedure.

It is my view that the regulation became *final for purposes of calculating the 90 day period* in which to file a petition in the court of appeals on 30 May 1975. Before this date, ICMAD could not be certain that it

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[96] *See, S.E.C.* v. *Chenery Corp.*, 318 U.S. 80, 94 (1943).

would be "adversely affected" in such a way as to justify and support a judicial challenge. I shall not provide a lengthy exposition of this conclusion but, rather, challenge the majority to explain *how* it could become final on an earlier date, either 17 October 1973 or 3 March 1975, and how the subsections could be logically divided.

Faced with the choice of either date as final, if the petitioner's plea can be denied as untimely, the majority has opted for 17 October 1973 rather than 3 March 1975. In so doing it has given support to the most desperate efforts of the Commissioner to avoid judicial review at all costs. The majority says: "Nor can ICMAD's challenge be deemed timely filed as an attack on the amendments promulgated in 1975, for the amendments merely provided exemptions to labeling and alternate means of compliance; they did not change the substance of the original regulation." [97] The answer to this is threefold: First, this is a deplorable acquiescence in the Commissioner's deceitful effort to deny that what ICMAD filed were "objections" as called for by the statute, and to preclude judicial review by terming them "petitions for amendment," discussed p.11 *supra*. Second, twelve subsection "amendments" added 17 months later are pretty strong evidence that the 17 October 1973 five subsections were *not* a final regulation after all, and that *all* subsections together constitute the regulation. Third, surely ICMAD has *some* opportunity at *some time* to object to these amendments of 3 March 1975; when should ICMAD have done so? My colleagues' answer is 90 days after 17 October 1973, before they were promulgated.

On this point the majority adds: "The amendments had nothing to do with the claims ICMAD now makes before this court." [98] These 12 new subsections of the regulation had *everything* to do with ICMAD's claims here. Not until these 12 additional subsections were promulgated was the FDA rulemaking complete. The 12 new subsections are as much part of the regulation as the original five; not until the full regulation had been announced did ICMAD know whether it had cause to object, to ask for modifications, or to file for judicial review. It filed objections within 30 days, and sought judicial review within 87 days after the FDA response. The 3 March 1975 amendments, adding 12 subsections to the original 5, were the key action of the Commissioner in the whole long drawn process, and the first action which carried any indication whatsoever of intended finality.

[97] Maj. op. 11.

[98] Maj. op. 13-14.

My colleagues have thus avoided justifying the manifest unfairness of requiring the petitioner to seek judicial review in less than 48 hours after receiving the FDA response, which was the FDA counsel's final position at argument. My colleagues have embraced, though, the difficulties inherent in explaining the Commissioner's proviso in the 17 October 1973 order calling for objections and comment within 30 days, his continuous informal exchange of views with many interested parties over a period of 17 months, the *un*published "Tentative Revised Final Order of 24 July 1974, the *additional twelve subsections* in the 3 March 1975 order, and the division in that same order of the cosmetic labelling regulation into *three categories* by the long delayed promulgation of a stay of two of the original subsections.

My colleagues may characterize this 17 October 1973 order as imbued with administrative finality; I say such characterization is administrative absurdity. If the majority is to charge petitioner ICMAD with the running of the 90 day period after the "final" order of 17 October 1973, then the majority opinion should answer (in addition to the difficult explanations listed above) some very practical subsidiary questions which naturally arise:

1) Would this court have accepted review at a time when the administrative proceeding was still going?

2) How can such review be reconciled with concepts of ripeness as developed by the Supreme Court and this court?

3) What record would have been transmitted to this appellate court? Would it have included proceedings subsequent to 17 October 1973?

4) What impact would the orders of 24 July 1974 and 3 March 1975 have had on the ongoing judicial review of the order of 17 October 1973?

5) Why were the effective dates for the regulation changed so often, and why did the "two" regulations have to go into effect at the same time?

I suggest that these questions cannot be satisfactorily answered. If the majority suggests that a petition for appellate review would have been appropriate during the 90 day period subsequent to 17 October 1973, I in turn respectfully suggest that any other panel of this court would have denied the petition for lack of ripeness. To reiterate, ICMAD has been placed in a truly "no-win" dilemma.

The majority have approved a model which, if followed by other administrators, can be used to insulate their own actions from judicial review. I would, as an alternative to having the district court review this matter initially, allow the petition here as being timely filed.

I must dissent.

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 75-1845

September Term, 1977

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., *Petitioner*

v.

UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

and

UNITED STATES FOOD AND DRUG ADMINISTRATION, DONALD KENNEDY, Commissioner of Food and Drug Administration, *Respondents*

and consolidated case No. 76-1007

BEFORE: ROBB and WILKEY, *Circuit Judges*; and GESELL*, *U.S. District Judge for the District of Columbia.*

Order

(Filed April 11, 1978)

Upon consideration of petitioner's petition for rehearing filed herein on February 27, 1978, and it appearing that petitioner has lodged an amendment to the petition for rehearing in the Clerk's Office, it is

ORDERED by the Court that the Clerk is directed to file petitioner's amendment to the petition for rehearing and to enter same on the docket, and it is

FURTHER ORDERED by the Court that petitioner's aforesaid petition is denied.

Per Curiam

For the Court
/s/ GEORGE A. FISHER
George A. Fisher
Clerk

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* Sitting by designation pursuant to Title 28, U.S.C. § 292(a).

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

(Caption Omitted in Printing)

BEFORE: WRIGHT, *Chief Judge*; BAZELON, MCGOWAN, TAMM, LEVENTHAL, ROBINSON, MACKINNON, ROBB and WILKEY, *Circuit Judges*.

Order

(Filed April 11, 1978)

The suggestion for rehearing *en banc* filed herein by petitioner, having been transmitted to the full Court and no Judge having requested a vote with respect thereto, it is

ORDERED by the Court *en banc* that petitioner's aforesaid suggestion for rehearing *en banc* is denied.

Per Curiam

For the Court

/s/ GEORGE A. FISHER
George A. Fisher
Clerk

APPENDIX G

Statutes and Regulations Involved

STATUTES

15 U.S.C. § 1454

(a) The authority to promulgate regulations under this chapter is vested in (A) the Secretary of Health, Education, and Welfare (referred to hereinafter as the "Secretary") with respect to any consumer commodity which is a food, drug, device, or cosmetic, as each such term is defined by section 321 of Title 21; and (B) the Federal Trade Commission (referred to hereinafter as the "Commission") with respect to any other consumer commodity.

* * * *

(c) Whenever the promulgating authority determines that regulations containing prohibitions or requirements other than those prescribed by section 1453 of this title are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, such authority shall promulgate with respect to that commodity regulations effective to—

(1) establish and define standards for characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this paragraph shall not be construed as authorizing any limitation on the size, shape, weight, dimensions, or number of packages which may be used to enclose any commodity;

(2) regulate the placement upon any package containing any commodity, or upon any label affixed to such commodity, of any printed matter

stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents;

(3) require that the label on each package of a consumer commodity (other than one which is a food within the meaning of section 321(f) of Title 21) bear (A) the common or usual name of such consumer commodity, if any, and (B) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged; or

(4) prevent the nonfunctional-slack-fill of packages containing consumer commodities.

For purposes of paragraph (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reasons other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such package.

15 U.S.C. 1455

(a) Regulations promulgated by the Secretary under section 1453 or 1454 of this title shall be promulgated, and shall be subject to judicial review, pursuant to the provisions of subsections (e), (f), and (g) of section 371 of Title 21. Hearings authorized or required for the promulgation of any such regulations by the Secretary shall be conducted by the Secretary or by such officer or employee of the Department of Health, Education, and Welfare as he may designate for that purpose.

21 U.S.C. 371

• • • •

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501 (b), or 502 (d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested persons, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall made such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition for the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceedings before the Secretary the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

REGULATIONS

21 CFR

§ 2.83 Burden of proof.

(a) At any hearing held as provided in section 701 of the act, the originator of the proposal or petition for the issuance, amendment, or repeal of any regulation contemplated under section 701(e)(1) of the act, shall be, within the meaning of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)), the proponent of the rule or order, and accordingly shall have the burden of proof.

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§ 2.86 Proposals and petitions.

(a) The Commissioner, under the authority delegated to him by the Secretary (21 CFR 2.120), on his own initiative or upon petition filed with him by any interested person stating reasonable grounds therefor, shall publish in the FEDERAL REGISTER any proposal or petition to issue, amend, or repeal any regulation contemplated under the following sections of the act: Sections 401, 403(j), 404(a), 406, 501(b), 502 (d), (h), and (n), 506(c), 507(f), 706(b) and (c); and sections 4 and 5 of the Fair Packaging and Labeling Act, and sections 2 (q)(1)(B) and 3(a) (2) of the Federal Hazardous Substances Act.

(b) Such published notices will provide for a time period of not less than 30 days within which all interested persons may present their views and comments thereon in writing.

(c) As soon as practicable after the expiration of the time for filing views and comments the Commissioner shall publish in the FEDERAL REGISTER his order acting upon such proposal or petition. Except as provided in § 2.67, this order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under this section.

§ 2.87 Objections to the Commissioner's order and requests for hearings.

(a) On or before the 30th day after the date of the publication of the Commissioner's order in the FEDERAL REGISTER as specified in § 2.66(c), any person who will be adversely affected by such order, if placed in effect, may submit objections thereto to the Commissioner and request a public hearing on the stated objections.

(b) These objections shall be accepted for filing only when they comply with all the following provisions:

(1) Objections shall be received by the Hearing Clerk if postmarked on or before the 30th day after the date of publication of the Commissioner's order in the FEDERAL REGISTER.

(2) Each objection to a provision of the Commissioner's order shall be separately numbered.

(3) Objections must establish that the objector will be adversely affected by the order.

(4) Objections must specify with particularly the provisions of the order to which objection is taken.

(5) Objections must be supported by reasonable grounds which, if true, are adequate to justify the relief sought.

(c) If the statement of objections is not accepted for filing because of failure to comply with paragraph

(b) of this section, the Commissioner shall so inform the objector and state the reasons for refusing to file the objections.

(d) If objections to the Commissioner's order issued pursuant to a petition are filed by a person other than the petitioner, the Food and Drug Administration shall mail a copy of the objections to the petitioner at the address given in the petition. Petitioner shall have 2 weeks from the date of receipt of the objections to make written reply.

(e) As soon as practicable after the time for filing objections has expired, the Commissioner shall publish a notice in the FEDERAL REGISTER specifying those parts of the order that have been stayed by the filing of objections or, if no objections have been filed, stating that fact.

PUBLIC HEARINGS AND NOTICE THEREOF

§ 2.88 Hearings under sections 507(f) and 701(e) of the act.

(a) Under the authority delegated to him by the Secretary (21 CFR 2.120), the Commissioner on his own initiative or upon a petition of any interested person adversely affected stating reasonable ground therefor, shall hold a public hearing for the purpose of receiving evidence relevant and material to the issues raised by objections filed pursuant to § 2.67 to any order to issue, amend, or repeal any regulation contemplated by any of the following sections of the act: Sections 401, 403(j), 404(a), 406, 501 (b), 502 (d), (h), and (n), 506(c), 501(f) and 706 (b), (c), and (d); and sections 4 and 5 of the Fair Packaging and Labeling Act, and sections 2(q)(1)(B) and 3(a)(2) of the Federal Hazardous Substances Act.

(b) Concurrently with the action taken pursuant to § 2.67, if a proceeding is stayed by the filing of ob-

jections, and a public hearing is requested, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice reciting the receipt of objections, those parts of the order that have been stayed by the filing of objections, and announcing that a public hearing will be held to receive evidence on the issues raised by such objections.

§ 2.89 Notice of hearing.

(a) As soon as practicable after a request for a public hearing has been filed, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice of hearing.

(b) The notice of hearing shall set forth the following information:

(1) A statement of the provisions of the order to which objections have been filed, and a summary of the objections.

(2) A statement of the issues raised by the objections.

(3) The designation of the presiding officer to conduct the hearing.

(4) The place where the hearing will be held.

(5) The time within which written appearances must be filed.

(6) The time (not earlier than 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER) when the hearing will commence.

No. 78-65

In the Supreme Court of the United States

OCTOBER TERM, 1978

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

v.

THE UNITED STATES DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ET AL.

INDEPENDENT COSMETIC MANUFACTURERS AND DISTRIBUTORS, INC., PETITIONER

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JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 4a-66a) is reported at 574 F.2d 553. The decision of the district court (Pet. App. 1a) is not reported.

JURISDICTION

The judgments of the court of appeals (Pet. App. 2a-3a) were originally entered on January 27, 1977, and were re-entered (Pet. App. 5a) on February 13, 1978. A timely petition for rehearing was denied by that court on April 11, 1978 (Pet. App. 67a). The petition for writ of certiorari was filed on July 10, 1978. The jurisdiction of the Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the district court had concurrent jurisdiction to review regulations promulgated by the Commissioner of the Food and Drug Administration (FDA) when review in the court of appeals is specifically authorized by statute.

2. Whether petitioner's petition for review by the court of appeals of an FDA regulation requiring ingredient labeling on cosmetics was untimely under 21 U.S.C. 371(f), when it was filed more than one and one-half years after the regulation was promulgated.

3. Whether the court of appeals correctly found that petitioner was not prejudiced by the procedures followed by the Commissioner in promulgating the basic ingredient labeling regulation and amendments to it.

STATEMENT

1. The Fair Packaging and Labeling Act (FPLA), 15 U.S.C. 1451 *et seq.*, grants the Secretary of

Health, Education, and Welfare authority to promulgate regulations establishing labeling or packaging requirements or prohibitions whenever he determines that such regulations "are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity * * *."

On February 7, 1973, the Commissioner of Food and Drugs [1] filed a notice of proposed rulemaking on a regulation requiring ingredient labeling, in order of predominance, on all cosmetics (38 Fed. Reg. 3523-3525). After receipt of 291 comments from interested parties,[2] the Commissioner, on October 17, 1973,

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[1] The Secretary's authority under the FPLA has been delegated to the Commissioner. 21 C.F.R. 5.1.

[2] Several of those commenting contended that the Commissioner did not have authority to establish ingredient labeling across the board, but was required to promulgate regulations on a commodity-by-commodity basis. The Commissioner concluded, however, that the FPLA contained ample authority to promulgate the regulation since all cosmetics could be considered a single commodity (38 Fed. Reg. 28912). He also observed that effective relief in this instance could be obtained with a comprehensive order governing all cosmetics and that cosmetic ingredient labeling was necessary to prevent deception of consumers and to facilitate value comparisons (38 Fed. Reg. 28912). In response to certain comments, the Commissioner included in the final regulation a procedure to facilitate the preservation of trade secrets, and further modified the proposed regulation in the following ways: (1) to permit placement of the ingredient statement on any appropriate information panel, rather than just on the principal display panel; (2) to recognize the Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary as the controlling source for the ingredient name to be used in label declaration; and (3) to exempt from the label declara-

published the regulation in final form, to be incorporated in the FDA regulations as 21 C.F.R. 701.3 (38 Fed. Reg. 28912-28914). The regulation (hereinafter the October 1973 regulation) was made applicable to all cosmetic labels ordered after March 31, 1974, and to all cosmetic products labeled after March 31, 1975 (38 Fed. Reg. 28914). Those filing objections were required to do so within 30 days.[3] Although 13 persons filed objections and four of them requested a hearing, all the objections were narrowly drawn [4] and none made a general challenge to the ingredient labeling requirement as such (39 Fed. Reg. 27181). Petitioner, Independent Cosmetic Manufacturers and Distributors, Inc., did not file comments concerning the proposed regulation or objections to the regulation as published in final form on October 17, 1973.

tion requirement the ingredients in each fragrance and flavor, as well as in various "bases" such as those used in shampoo concentrates (38 Fed. Reg. 28912-28913).

[3] Under 21 U.S.C. 371(e)(2), objections to an order involving the issuance of a regulation must be filed "[o]n or before the thirtieth day after the date" on which the order is made public.

[4] The requests for a hearing involved only three aspects of the regulation: (1) the declaration of each ingredient in a color; (2) the labeling of small packages held in compartmental trays or racks; and (3) the time for compliance with the labeling requirements (40 Fed. Reg. 8922) (R. 546-551, 553, 560-564, 580-583, 587-589). The other objections, on which a hearing was not requested, concerned the following matters: (1) the listing of an ingredient substitute for another in short supply (R. 585-586); (2) the listing of a flavor or fragrance by words describing the flavor or fragrance rather than by the ingredients therein (R. 558-559); (3) the 1/16th-inch requirement with respect to the minimum-size type for listing ingredients (R. 541-542); (4) the use of the phrase "and other ingredients" where an ingredient is exempted from public disclosure (R. 539-540); and (5) the disclosure of specialty blends and color blends (R. 547-548).

After informal discussions with the objectors and others (40 Fed. Reg. 8918), the Commissioner, on July 25, 1974, announced the availability to the public of a draft order that "meets the objections [to the October 1973 order] and eliminates any need for a public hearing." 39 Fed. Reg. 27181. Further comments and discussion were solicited. *Ibid.* Petitioner reviewed the draft order, submitted comments, and twice met with FDA officials to discuss them (R. 740, 783, 895, 962, 964, 982).[5]

On March 3, 1975, the Commissioner published an order providing limited exemptions and supplemental procedures for listing certain ingredients (40 Fed. Reg. 8918-8924) (hereinafter the March 1975 amendments). These were to be in addition to the "basic provisions requiring cosmetic ingredient labeling" in the October 1973 regulation (40 Fed. Reg. 8921).[6]

[5] "R." refers to the agency record that was filed in the court of appeals in No. 75-1845, the proceeding on the petition to review (see page 9, *infra*).

[6] For example, the basic regulation required that all ingredients be listed in descending order of predominance. 21 C.F.R. 701.3(a); 38 Fed. Reg. 28913. Under the March 1975 amendments, ingredients other than color additives present at a concentration of less than one percent could be listed at the end in any order, and this could be followed by a listing

In a separate independent order issued on March 3, 1975 (40 Fed. Reg. 8924-8926) the Commissioner disposed of the objections filed with respect to the October 1973 regulation. He found no merit in most of the objections (40 Fed. Reg. 8924-8925); but he stayed the operation of, and directed a hearing on, the requirement that each color ingredient be declared, and on the issue whether to provide for off-package labeling for small cosmetic items in compartmented trays or racks (40 Fed. Reg. 8925). In response to the objections asking that the time for compliance be lengthened, the Commissioner extended the effective date of the regulations to March 3, 1976, for all labels ordered, and to September 3, 1976, for all cosmetic products labeled. *Ibid.* Thereafter, the four objectors who had requested a hearing withdrew their objections. 40 Fed. Reg. 23460. Accordingly, on May 30, 1975, the Commissioner terminated the partial stay. *Ibid.* The regulation is now in effect. 21 C.F.R. 701.3.

2. On April 1, 1975, petitioner filed papers which purported to be objections to the March 1975 amendments (R. 1079). The principal thrust of petitioner's objections, however, was that petitioner was "[i]n general * * * totally" opposed "to the concept of ingredient labeling on cosmetics" (R. 1079). Petitioner argued that ingredient labeling would enable competitors to learn cosmetic formulas and would also

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of color additives also without respect to predominance. 21 C.F.R. 701.3(f); 40 Fed. Reg. 8919.

involve "great cost" for label changes (R. 1079-1080). Petitioner challenged 21 C.F.R. 701.3 in its "entirety" as unnecessary to prevent consumer deception or to facilitate value comparison (R. 1080-1081). Petitioner also objected to the March 3, 1975, amendments on the general ground that they were "arbitrary and unreasonably onerous" (R. 1081-1082). Petitioner then proceeded to propose as an "alternative" that ingredients be listed alphabetically or that only known allergens be listed (R. 1082-1083).[7] Petitioner demanded a hearing on all its objections (R. 1087).

The Commissioner rejected petitioner's general objection to ingredient labeling on the ground that this issue was raised by the October 1973 order and that petitioner's April 1975 objection was therefore untimely. 40 Fed. Reg. 23458. He also rejected petitioner's objections dealing with the March 1975 amendment, concluding that these objections did not raise factual issues warranting a hearing but were in fact requests "that additional exemptions be granted or alternative methods of labeling be permitted." *Id.* at 23459. Under the Act, the proper procedure for proposing additional exemptions was not, the Commissioner stated, to file "objection[s] to ex-

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[7] Petitioner also objected to (1) the "scrambling" only of those non-color ingredients below the 1% level, (2) the limitation of "off-package" labeling to tightly compartmented trays or racks, and (3) the restriction on the option of placing a "new ingredient" list inside the carton to products with ingredient changes resulting from ingredient shortages (R. 1084-1087).

emptions granted," but rather to file "a petition to amend the regulation imposing the requirement." *Ibid.*[8]

3. On August 27, 1975, petitioner filed suit in the United States District Court for the District of Columbia, requesting that the court declare the ingredient labeling regulation unlawful and enjoin the Commissioner from enforcing the regulation (A. 13).[9] Petitioner alleged that the basic regulation was unlawful under the FPLA for the following reasons: (1) the FPLA requires that ingredient labeling be done on a commodity-by-commodity basis and cosmetics are not a single commodity; (2) there was not an adequate determination, as required by the FPLA, that the regulation was necessary to prevent deception of consumers or to facilitate value comparisons; and (3) the regulation would, contrary to provisions of the FPLA, require the divulgence of trade secrets (A. 8-10). The complaint also alleged various procedural irregularities including, among others, (1) the failure to hold a hearing on "the basic issues raised" by the regulation, (2) the failure to

[8] The Commissioner set down for hearing the question whether it is reasonable to establish a level of concentration (in this case, 1%) below which cosmetic ingredients need not be listed in descending order of predominance. He stayed the pertinent parts of the regulation (21 C.F.R. 701.3(f)(1) and (2)) pending the outcome of the hearing. 40 Fed. Reg. 23458.

[9] "A." refers to the abbreviated joint appendix to the briefs filed in the court of appeals.

publish the proposed amendments for comment (A. 10-13). The complaint was dismissed by the district court for want of subject matter jurisdiction (Pet. App. 1a).

On August 27, 1975, petitioner also filed a petition for review of the regulation in the United States Court of Appeals for the District of Columbia Circuit on the same theories it advanced in the district court (Pet. App. 12a-18a). The petition was consolidated with petitioner's appeal from the district court decision (Pet. App. 5a-6a).

The court of appeals affirmed the district court. The majority observed that judicial review provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(f), made applicable to FPLA regulations by 15 U.S.C. 1455(a), provided for exclusive jurisdiction in the court of appeals, absent agency action which is *ultra vires* (Pet. App. 6a). It concluded that the conduct of the Commissioner was not *ultra vires* because there was no showing of a "patent violation" of agency authority (Pet. App. 7a). The court of appeals also denied the petition for review. It held that the August 1975 petition for review was untimely because it was not filed within 90 days of the October 1973 order promulgating the regulation, as required by 21 U.S.C. 371(f)(1). Regarding petitioner's claim that its failure to file its petition attacking the basic regulation within the prescribed 90-day period was attributable to procedural irregularities occurring in the promulgation and amendment of the regulation, the court of appeals found

(Pet. App. 15a-17a) that the alleged procedural irregularities related to matters having nothing to do with petitioner's basic challenge to the regulation. The court thus concluded (Pet. App. 16a-17a) that if there were procedural infirmities, petitioner was not prejudiced by them.[10]

ARGUMENT

The decision of the court of appeals is correct and it does not conflict with any decision of this Court or any other court of appeals. Accordingly, it does not warrant further review.

1. Petitioner contends (Pet. 11-17) that the district court had concurrent jurisdiction, pursuant to 21 U.S.C. 371(f)(6), to review the regulation promulgated by the Commissioner. However, as the court of appeals properly concluded, the regulations challenged by petitioner in the district court could have been challenged by a timely petition for review in an appropriate United States Court of Appeals. 15 U.S.C. 1455(a); 21 U.S.C. 371(f). Where Congress has expressly provided "a procedure for judicial review of administrative action, that procedure is the exclusive means of review unless, because of some extraordinary circumstances, the procedure fails

[10] Circuit Judge Wilkey, dissenting, was of the view that the FPLA conferred jurisdiction on the district court and that the petition for review in the court of appeals was timely because the October 1973 regulation was not a final agency action that would warrant judicial review (Pet. App. 19a-66a).

to provide an adequate remedy" (Pet. App. 6a).[11] See also *Nader* v. *Volpe*, 466 F.2d 261, 271 (D.C. Cir. 1972). This Court's decision in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), relied upon by petitioners (Pet. 12-13), supports this result. *Abbott* involved the question whether there could be pre-enforcement judicial review of the Commissioner's action in promulgating a regulation not subject to the special statutory review procedure in 21 U.S.C. 371(e)-(g) or to any other statute expressly providing for judicial review. 387 U.S. at 146-147. Since there was no other adequate remedy, the Court, relying in part upon the savings clause in 21 U.S.C. 371(f)(6), cited by petitioners in this case, held that the district court had jurisdiction to afford equitable relief. 387 U.S. at 140-144. The Court was, however, careful to distinguish the regulation before it from one, like the regulation at issue in this case, that is subject to the special review provisions of 21 U.S.C. 371(e)-(g). 387 U.S. at 145-146.[12] See *Whitney National Bank* v. *Bank of New Orleans and Trust*

[11] As the court of appeals noted (Pet. App. 9a), any other rule would permit an aggrieved party which had slept on its rights to bypass the 90-day time limit within which it must file a petition for review in the court of appeals, pursuant to 21 U.S.C. 371(f)(1), as petitioner tried to do in this case (see pages 12-13, *infra*).

[12] The Court quoted with approval the Notes of the Advisory Committee on the Federal Rules of Civil Procedure, Rule 57: "A declaration [by the district court] may not be rendered if a special statutory proceeding has been provided for the adjudication of some special type of case * * *." 387 U.S. at 146 n.13.

Company, 379 U.S. 411, 421-422 (1965). Thus, since judicial review by a court of appeals was available, the district court lacked jurisdiction, absent "extraordinary circumstances" not present here (Pet. App. 6a), to hear this case.

2. Petitioner contends (Pet. 20-23) that the order promulgating the basic regulation in October 1973 was not a "final order" from which an appeal could be taken because the Commissioner later amended the basic regulation on May 30, 1975. It thus argues that, notwithstanding the requirement in 21 U.S.C. 371(f)(1) that a petition for review of an agency order promulgating a regulation be filed within 90 days of the "day such order is issued," its review petition was timely because it was filed within 90 days of the date the amendments were promulgated.

The court of appeals (Pet. App. 14a-15a) properly rejected this contention. Petitioner's challenge is to the legality of the basic regulation adopted in the October 1973 order. That regulation was promulgated in final form, after comment, with an effective date. The impact upon petitioner's members was direct and immediate in that they were compelled to make immediate preparations for label changes. Nothing more is required to make an order final and thus reviewable. *Abbott Laboratories* v. *Gardner*, *supra*, 387 U.S. at 148-153; *Port of Boston Marine Terminal Association* v. *Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970).

That the effective date on the regulation was postponed, or that there were later amendments provid-

ing limited exceptions to the basic regulation, does not make the October 1973 order any less final for judicial review purposes.[13] At the very least, the October 1973 regulation represented the "actual application of the [ingredient-labeling] plan in its initial stage." *Panhandle Eastern Pipe Line Co.* v. *Public Service Commission of Indiana*, 332 U.S. 507, 512 (1947). In such circumstances, a party need not wait for a later order before contesting the action already taken. *Ibid.* Had petitioner filed a timely petition for review in the court of appeals, the court would have considered petitioner's challenge to the October 1973 regulation on its merits, as it has reviewed appeals from agency actions whose finality was arguably far less clear than that here. *Independent Bankers Association of America* v. *Smith*, 534 F.2d 921, 926-930 (D.C. Cir. 1976); *Goodman* v. *Public Service Commission*, 467 F.2d 375, 377-378 (D.C. Cir. 1972); *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F.2d 584, 589 and n. 8 (D.C. Cir. 1971).

3. Petitioner contends (Pet. 17-20) that various alleged procedural errors effectively precluded it from participating in the promulgation of the regulation and "eclipsed" its right to judicial review. These

[13] If a party were permitted to challenge the legal basis for an agency regulation years after it was promulgated in final form simply because amendments to the regulation had been entertained, the agency might well be discouraged from considering and making salutary changes or amendments to the basic regulations. It would also be unfair to the agency and to those regulated who have acted in reliance on the absence of any initial challenge to the legality of a regulation.

contentions were carefully considered and properly rejected by the court of appeals (Pet. App. 15a-17a).

The procedures followed by the Commissioner in this case were "at least in part, invited by the objectors" to the regulation (Pet. App. 7a), and those procedures ultimately resulted in the withdrawal of the objections. In any event, none of the alleged errors prejudiced petitioner's ability to seek judicial review. Thus, the Commissioner's failure to hold a hearing on objections to the October 1973 regulation could not have prejudiced petitioner, because the arguments it subsequently raised were unrelated to the narrow issues raised in the objections.[14] For the same reason, petitioner was not prejudiced by the Commissioner's failure to publish promptly a notice indicating what parts of the October 1973 order had been stayed by the filing of objections. The provision for a stay in 21 U.S.C. 371(e)(2) is, as the court of appeals observed (Pet. App. 17a), independent of the requirement in Section 371(f)(1) that petitions for review be filed within 90 days after an order issuing a regulation is issued.

Nor was petitioner prejudiced by the Commissioner's failure to publish the proposed amendments on July 24, 1974, prior to their promulgation in final form on March 3, 1975 (Pet. 18). Those amendments

[14] The objectors were later able to resolve their differences with the Commissioner and withdrew their request for a hearing (see page 6, *supra*). Under the statute, the Commissioner is required to hold a hearing only where there is a request for one. 21 U.S.C. 371(e)(3).

were unrelated to the basic labeling requirement announced in the October 1973 regulations to which petitioner now belatedly objects. In any event, the record reflects that petitioner was able to review the proposed amendments, comment upon them, confer with FDA officials concerning them, and object to them (page 5, *supra*).

In sum, petitioner slept on its rights, neither filing objections to the October 1973 regulation nor filing a petition for review within 90 days after its promulgation. Complaining of unrelated procedural irregularities, petitioner now seeks to circumvent statutory requirements for review. The court of appeals properly declined to create a special exemption (Pet. App. 17a).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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